1 UNITED STATES DISTRICT COURT 2 FOR THE DISTRICT OF ARIZONA 3 4 In Re: Bard IVC Filters ) MD-15-02641-PHX-DGC Products Liability Litigation 5 ) Phoenix, Arizona 6 ) January 29, 2016 7 8 9 10 11 12 BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE 1.3 REPORTER'S TRANSCRIPT OF PROCEEDINGS 14 STATUS HEARING 15 16 17 18 19 20 21 Official Court Reporter: Patricia Lyons, RMR, CRR 22 Sandra Day O'Connor U.S. Courthouse, Ste. 312 401 West Washington Street, SPC 41 23 Phoenix, Arizona 85003-2150 (602) 322-7257 24 Proceedings Reported by Stenographic Court Reporter 25 Transcript Prepared with Computer-Aided Transcription

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08:31:12 1 PROCEEDINGS 2 THE COURTROOM DEPUTY: MDL 2015-2641, Bard IVC 3 4 Filters products liability litigation, on for a status 09:03:17 conference. THE COURT: All right. Let's have plaintiffs' lead 6 7 counsel and defense counsel identify yourselves for the 8 record. I don't think we need to have everybody in the courtroom or on the phone do that. 09:03:29 10 MR. BOATMAN: Good morning, Your Honor. Bob Boatman 11 for plaintiffs from Gallagher & Kennedy. 12 THE COURT: Let me pause just a minute. 13 Can you hear that ticking? That's because somebody has their cell phone on. Muted isn't enough; it still 14 09:03:44 15 interferes with the system. MR. LOPEZ: Airplane mode isn't enough --16 17 THE COURT: Yeah, airplane mode doesn't do it; it still interferes. So what I need to do is have you all turn 18 off your cell phones, if you will, and that way we won't have 19 09:03:54 20 that kind of interference. 21 All right. Sorry, Mr. Lopez. Let's go ahead. 22 MR. LOPEZ: I apologize. 23 Ramon Lopez, Lopez McHugh, co-lead counsel for the 24 plaintiffs' PLC.

THE COURT: Somebody still has their phone on.

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09:04:10 1 MR. STOLLER: Paul Stoller for plaintiffs, 2 your Honor. 3 THE COURT: Good morning. 4 MR. NORTH: Good morning, Your Honor. Richard North 5 on behalf of the defendants. 09:04:13 6 MR. CONDO: Your Honor, good morning. Jim Condo on 7 behalf of the defendants. 8 MR. LERNER: Matthew Lerner on behalf of the 9 defendants. 09:04:23 10 THE COURT: All right. So good morning to all of 11 you. Good morning to the folks on the phone. Happy new year. 12 Welcome back to Phoenix. 13 Counsel, my thought in these hearings is that we -and I didn't tell Traci this beforehand, I should have, but 14 that we don't need to get the names of all of the lawyers on 09:04:38 15 the phone or those in the courtroom since we have designated 16 17 counsel to take the lead for plaintiffs, and that's really the 18 key. Would everybody please double-check your phones. 19 Let's take a minute. Everybody look at your phone, even if 09:04:54 20 you think it's off, and let's just make sure they're off. 21 22 That way we'll not have that interference. 23 My thought is what we really need to do is just get 24 on the record the presence of lead counsel. 09:05:14 25 Are you all in agreement with that from the plaintiff

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side?

MR. LOPEZ: Yes, Your Honor.

MR. BOATMAN: Yes, Your Honor.

THE COURT: Okay.

Okay. Let me tell what you I'd like to do or the order in which I'd like to do things this morning. We've got a number of different matters that are teed up for today from the last case management conference. And I think the order in which I'd like to address them is this: I'd first like to get any additional thoughts you have on the Lehmann motion for a protective order. Since that's the last thing I read, I'd like to take it first because I'll forget much of it in the rest of the hearing.

It might be the phone line.

Then I want to talk through general case management matters. I've got a few questions to ask, but I want to talk through the various issues that are identified in your joint report that is at Docket 451. And I think I want to talk through them in the order that it's in the report rather than the agenda that you provided that I sent back out. We'll cover that material, but I want to go through it in the order in the report.

After that, the other matters I'd like to address are the privilege log issues and how we're going to solve that problem. There are a couple of stipulations that have been

09:06:38 1 submitted we'll need to address. I'd like to get a report on 2 the status of coordination with the state court litigation, as 3 well. 4 Anything we can do on that static, Traci? 09:06:53 5 THE COURTROOM DEPUTY: I'm going to keep turning down the incoming to see if that will help. 6 7 THE COURT: Okay. 8 So that's the order I'd like to do things. 9 Let's start with the Lehmann report. I have read 09:07:01 10 your briefs. I have not had time yet to read the factual 11 materials submitted in support of the brief. I'm planning to 12 do that, but things got away from me this week and I didn't get time to actually go read those materials. 13 So I understand the arguments that have been made, I 14 09:07:24 15 think. I want to give each side a few minutes to cover any 16 thoughts you have now that briefing is finished to make sure 17 I'm getting the big picture, and then I've got some specific questions for you. 18 This is the defendants' motion, so why don't we start 19 with one of defense counsel and any summary thoughts you want 09:07:40 20 to share. 21 2.2 MR. NORTH: Your Honor, if I understand the Court's 23 interest right now, it's not for formal argument, but just to 24 raise any additional issues? 09:07:53 25 THE COURT: Well, this is your opportunity. I'm not

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going to schedule another argument. So if there's points you want to make, then by all means make them now. So in that sense it's formal argument. But my point is you don't need to start at the beginning and repeat all of your arguments because I've read the briefs so I understand the basic positions.

MR. NORTH: Okay. Thank you, Your Honor.

And I think that our position is, I hope, fairly set out in the briefing. This is an issue, as the Court knows, that has been decided in — there are 15 decisions on this question throughout the country, and not only are the positions set forth in the briefing, but I think they're also set forth in many of those other orders from your colleagues throughout the country.

I think one of the issues that maybe was not addressed as extensively as it could have been in the briefing is whether there is need for additional discovery or additional depositions because of new plaintiffs or different counsel involved.

And I did want to point out for the Court the fact that out of the 15 published decisions on this issue, the precise same issue, that have been issued throughout the country, members of the plaintiffs' steering committee in this MDL represented the plaintiffs in 14 of those 15 cases. So the very same plaintiffs attorneys that are leading this MDL

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have handled all of the discovery beforehand on the Lehmann issue and have been involved.

And for that reason, we believe that the evidentiary record that's set forth already in front of the Court, including the testimony of the two central witnesses that was given in Dallas in federal court where they were cross-examined by two members of the steering committee here, should be sufficient without further additional discovery on this issue.

We would note that courts throughout this country, with the exception of three courts, I believe it is, have found this document to be privileged under either the standard, the "because of" standard, for work product that's prevalent in the Ninth Circuit, and even under the more onerous "primary motivating factor" standard that's applicable in the Fifth Circuit. Three different courts have applied that standard and still found this document to be work product.

We think the critical issue here is that the testimony and the evidence is clear that this document was created for use in anticipation of litigation. The plaintiffs' entire arguments are basically that, well, it was used for business purposes afterward.

But that's not the test, Your Honor. We submit that the test is as to whether a document is work product is why it

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was created. And in this instance, the evidence from

Donna Passero, the lawyer at Bard, Dr. Lehmann, the consultant
who performed the analysis, the contract itself, everything is
unrefuted that it was commissioned and created in anticipation
of litigation.

The record is also clear that Bard had received threats of litigation. They had received patient complaints. They had received letters from attorneys at the time this was commissioned. They had also reported claims to their insurance company. There is clearly a record, we submit, of anticipation of litigation.

Now, the plaintiffs principal argument is not only that they claim we used this later for business purposes, which, as a number of courts have held, is not the test here, but they also tried to string together two very separate events and conflate Dr. Lehmann's role with the company in April of 2004 with his retention by the law department in December of 2004.

In April of 2004, he was finishing his tenure as an independent contractor as the interim medical director while the company attempted to hire a full-time medical director. They hired that medical director, Dr. Ciavarella, in May of 2004.

And while the plaintiffs have this conjectural theory that what Dr. Lehmann was doing for the law department in

December was part and parcel of something he was doing all year, there's no corroborating evidence of that. Nor could there be. There are no documents. There's no evidence that Dr. Lehmann is doing anything like this between the time he left the company as the interim medical director in December of 2004 and the time -- I mean in April of 2004, and the time that the law department hired him independently in November of 2004 to prepare this analysis to try to understand what the adverse event reports coming into the company meant.

So we believe that their theory that it was created for business purposes is based on conjecture, and conflating these two different roles, trying to collapse them chronologically, when there is no evidence to support that.

And the unrefuted evidence is that this was created for use in anticipation of litigation.

THE COURT: Hold on, Mr. North.

Traci, can we ask Brian Lalley to come up and see if there's anything we can do to fix that.

THE COURTROOM DEPUTY: I'm already trying.

THE COURT: Great.

All right. Go ahead.

MR. NORTH: As it states there, and I've mentioned, most of the other courts who have addressed this have found it to be work product. There are only three decisions out there that went against us on the work-product claim. One was a

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decision without explanation from a state court judge in San Diego. One was a decision from a magistrate in Florida in two cases. And on objection to that we filed with the district court judge, she looked at it very carefully, said it was a very close call, but that her magistrate did not have the evidentiary record at the time that he made his decision.

The third decision was by Judge Jones in the *Phillips* trial in Nevada. With all due respect to Judge Jones, he did not read our briefs. He would not allow us to brief it, actually. He would not look at the evidence. He handled the issue with oral argument for like five minutes in the middle of trial.

And respectfully, we believe he applied the wrong standard. And what they quoted in their brief as to what he said in the transcript demonstrates that he was basing his ruling on the later use of the document for business purposes and not as to why it was created. Which is the Ninth Circuit test.

So on -- for all those reasons, Your Honor, and for the reasons set forth in our brief, we do believe this document is work product.

THE COURT: Okay. Thanks, Mr. North. I've got a number of questions for you, but why don't we hear any thoughts from plaintiffs' counsel first.

MR. CLARK: Morning, Your Honor, Shannon Clark. May

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               I approach?
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                        THE COURT: Please.
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                        MR. CLARK: This motion has been extensively --
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                        THE COURT: Let me have you talk over at the lectern
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               here so everybody can hear you.
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                        MR. CLARK: I will try to focus on some of the
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               arguments raised in the defendants' reply memorandum, but I
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               think it's very important that when we look at this issue, you
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               are charged in evaluating the totality of the circumstances.
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               That's the law.
                        We focus on the document itself and the circumstances
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               surrounding creation of that document. You'll see that in the
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               grand jury case that you'll read; you'll see that in the
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               Ritchie case.
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                        And when you look at the document itself --
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                        THE COURTROOM DEPUTY: I apologize. Can you
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               double-check your connection? Because I'm not getting it now.
               We had it before we started.
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                        MR. CLARK: Let me try it.
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                        How's that?
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                        THE COURTROOM DEPUTY: All right. There you go.
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               You're up.
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                        MR. CLARK: I don't want to waste the Court's time,
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              but we'll get back to this.
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                        But when you look -- starting with the document
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itself, you will see that other than a stamp on the document that says it's submitted to the law department and it's attorney-client privileged communication, there is no indicia of any type of the things we usually see when we have work product.

THE COURT: Well, I was going to save my questions, but let me ask you a question about that up front.

MR. CLARK: Sure.

THE COURT: That argument doesn't work in my mind for this reason, and I'm saying it so you can tell me if I'm There's nothing in any case law or any rule that I wrong. understand that says the work product itself has to have litigation analysis or legal analysis or attorney thought process in it. An example is -- well, when I was a lawyer, I litigated environmental cases. And clients sometimes, when charged with groundwater contamination, would, through their attorneys, hire an environmental expert to come out, sample their groundwater, give them the results of the sampling in anticipation of litigation. The reports were nothing but groundwater analysis. Not a word about litigation, no strategy, no attorney thought process. And yet many cases have held that is work product because it was prepared in anticipation of litigation.

And in fact rule 26 itself says if substantial need is shown and you're going to turn over the work product, take

out of it the attorney mental impression, suggesting work product is more than attorney mental impressions.

So when I read this argument that if I look at the document there's no litigation strategy in it, that hasn't made sense to me.

MR. CLARK: And, Your Honor, I think you're right for the most part. But first of all, the document itself is part of the analysis because you have to ask yourself why was this report commissioned, and would it have been commissioned either way? Was it necessary for Bard's work?

And so part of that analysis under the totality of the circumstances is you look at the document. And our point there is the document itself doesn't contain any of the types of things we normally want to protect as far as attorney mental impressions. This is not a summary of witness interviews that counsel has directed an investigator go talk to people, ask them this, this, and that because I need to know for defense of my case. This is just basically an analysis that is commissioned.

THE COURT: How's that different than my expert's groundwater analysis? There's nothing in that that is attorney --

MR. CLARK: Let me get to that.

It's different in the sense that in your case, you are retained by a company to defend the groundwater analysis

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or prosecute it or something. Whatever the analysis is, you have a job as a lawyer to do that work.

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In this case we will see that the report itself is part and parcel of what Bard needed to do as a manufacturer of medical products. Medical devices. There are regulations, there are internal Bard employees who are relying on this information all along the way, and Dr. Lehmann himself is telling Bard they need this type of analysis.

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THE COURT: That sounds to me like a slightly different argument. I think what you're saying is not that the content of the report is unworthy of protection because it's not legal strategy, you're arguing that the content of the document is proof that it wasn't created in anticipation of litigation, that it was created for other company purposes. Am I right about that?

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09:20:20 15 Am I right about that?

MR. CLARK: That's correct. I'm not saying this document could not be subject to work product privilege. What I'm saying is this product is not because, as we will see, it served a purpose that is completely independent, that is in the ordinary course of Bard's business.

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So as far as the -- we can, I think, dispense with the document itself. I think we've got through that. But I think it is important when you look at these arguments, and I keep hearing it is not disputed, that the contract was entered in anticipation of litigation, it's not disputed that there

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wouldn't be a contract or there wouldn't be a report but for litigation. Well, it is disputed. It's disputed not only by Bard's witnesses, but by Bard's documents. And the first document you can start with is the actual law contract itself.

And I think you said you hadn't gotten through all the exhibits, but I would commend to your reading schedule A, which is the scope of work on defendants' Exhibit R, which is the November 15, 2004, contract. And I've got it blown up here, but you can see from all six of those items, those are all tasks that are part and parcel of Bard's work as a manufacturer of medical devices. These are all things that Bard has been doing up until this report, analyzing MAUDE data, looking at statistics, looking at sales. These are all things that were happening, starting with Dr. Lehmann's work in 2003 and going all the way through at least April of 2004.

So there's nothing specific about this scope of work that is suggestive of something you would need for legal advice, something you would need for strategy. This is the exact type of stuff that Bard needs to evaluate its product. Not only per the regulations, but also per what its own witnesses have said.

And in Exhibit 5 to our brief, you're going to see

Dr. Ciavarella, who says, yes, it is absolutely incumbent upon
the manufacturer to make sure it is doing a trending analysis,
and part of that is looking at MAUDE data.

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So MAUDE data and sales information does not appear for the first time in the Lehmann report, it appears in every HHE, the health hazard evaluation, that we have up through the Lehmann report. Not only the two prepared by Dr. Lehmann, but also the July one prepared with Dr. Lehmann's assistance by Dr. Ciavarella.

So what are we left with? We're left with the testimony of Ms. Passero and Dr. Lehmann himself. And as I mentioned before, both of them are disputed. We've talked about the standard which is that you have to look at this under the totality of the circumstances.

Now, what we see in this case is basically a tale of two Bards. We have Bard the litigant, who is saying that this was a unique situation commissioned by the law department, that it would not have been done except for the fact that there was a threat of impending litigation.

But when you look at the documents, which are Bard documents, you see that Bard the filter manufacturer uses this exact type of information from the scope of work in Dr. Lehmann's contract for the March 2004 HHE, for the April 2004 HHE, and for the July 2004 HHE.

When you look back to what Dr. Lehmann himself as —
in his role as part of the crisis communications team, which
is doing, for lack of a better word, damage control when Bard
perceives it is going to have a media problem with this and

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wanting to keep the message straight, Dr. Lehmann is the one who tells Bard, hey, one of the things we haven't covered in our messaging to the reps and media is the MAUDE database. And he says, if we get a reporter pressing questions on a number of reports, then we'll have to deal with this sticky issue. That means we have to have sales estimates and tabulations of MAUDE entries as already provided by BPV staff and calculations of -- as raised, and goes on to talk about who is going to have to deliver that message.

Well, what do we have in the Lehmann report?

Dr. Lehmann's report is, as he predicted back in April of

2004, an evaluation of MAUDE reporting rates, sales estimates.

He also analyzes bench testing, which was performed under his direction in Arizona months before this report was done, and you can see I reference to that in Exhibit 2, page 204.

Dr. Lehmann told the company that it needed to have. And it told the company that not as a consultant to the law department. This was long before the contract was even entered. It told the company that as a consultant to the crisis communication team and as part of the ongoing product analysis that Bard has an absolute responsibility to do as a manufacturer of products.

So the other thing you need to analyze as you're looking at the totality of the circumstances is what did Bard

actually do with the Lehmann report. And I heard Mr. North say that that is not the test, what actually happened.

But it is part of the test because you're looking at the circumstances here, and part of the circumstances and the questions that you have to analyze is would we have this report without the threat of litigation. And the answer is yes, because this report and what it did was something that Bard continued to use. It used the same data along the way in those three HHEs that predate the Lehmann report, but then after the Lehmann report — actually, let me take that back. Days before the final Lehmann report, Bard is, in fact, using all of Dr. Lehmann's data in its remedial action plan.

There's a December 9, 2004, six days before the final report, that uses every bit of that Lehmann report. You also will see the December 17 HHE, which uses extensive information. And we've done a table in our brief to show you the comparisons of that.

And we have seen the remedial action plan, which uses that exact same data and, in fact, attaches the Lehmann report to it. These are all things that are part of Bard's regulatory responsibilities.

THE COURT: Do you agree that the December 9th RAP was a draft of what became the January 4th RAP?

MR. CLARK: You know, I don't have specific information on that. It is substantially similar. It looks

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like there was some updating there. So my -- the point there is that before and after, this was being used in connection with Bard's ongoing responsibilities as a manufacturer.

And what's important here is we don't have anything in the record that shows us how this report was used by the lawyers. There's a very vague and generic statement by Ms. Passero that she commissioned the report to help the company analyze risk. But there's no risk analysis in this report. It just tells here's what the failure rates are. There's no other testimony about, hey, this went to other lawyers, this went to outside counsel to help develop litigation strategy. And so when you look at the record we do have, that's very, very important.

So, again, going back to this idea that there's a very big disparity between what we're hearing from Bard the litigant and what Bard the manufacturer is actually saying.

And this is important because, again, going to this idea that Ms. Passero's testimony is somehow not disputed. Bard's own documents, and if you look at Exhibit 3, what Bard is telling us is a consultant was commissioned by corporate senior management to provide an independent study of the risk and benefit of the recovery filter. So that is what Bard's business people think is happening and that's how they're approaching it and how they are using it.

We're hearing a different tale from Ms. Passero, but

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you have to look at the documents. These are Bard documents. These are not things that are conjecture from the plaintiffs and it's not isolated.

Look at Exhibit 13, section 3A, identification of the problem. As part of the ongoing evaluation of the RNF, Bard requested an independent study of the risks and benefits of the RNF with an emphasis on the use of bariatric surgery and trauma patients. These are part and parcel of what Bard does as a manufacturer of medical devices.

Again, we see it in the December 17, 2004, same description of the problem. Bard hired an independent consultant to help us assess this. And this is the context. This is stuff that it's doing as part of its regulatory responsibilities.

So where does the report go? Well, we hear from Ms. Passero it only went to people with a need to know, and that they were all instructed that they had to keep it confidential.

We hear a different story from Bard's witnesses.

Dr. Ciavarella tells us that he was given the report. He used it to help him prepare for — the HHEs, but he was not instructed that it was a secret document, he was not instructed to keep it confidential.

So that is in Exhibit 5 to our brief, and you will also see that again in the remedial action plans and the HHE.

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So we don't have the ability here without a hearing for you to evaluate the credibility of these witnesses in person, but I submit that when you look at the credibility as examined by in contrast to Bard's own documents and what Bard's other witnesses are saying, you will see that this is a document that undoubtedly was created because Bard needed to have this information. Just like Dr. Lehmann told them back in April of 2004.

examine the affidavits and the testimony of Ms. Passero, but as you do that and as you read through the hearing transcript in the Alexander case, it is very profound, the lack of depth of her understanding as far as the other aspects of the business, that she did not know what the regulatory requirements were for Bard. She did not know how Bard examined complaints for product failure. She did not know what was required of the company or what it was doing with this type of information before she hired Dr. Lehmann.

That's all very important because, yes, she can say that she hired him with the idea that he would prepare this report, and there's a credibility issue on that, but when you examine that carefully and look at what she didn't know, that is very telling because the standard here is would we have this document without the threat of litigation, and the answer is yes. Look at what she doesn't know.

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I also think we've heard a lot about the weight of authority and how other judges have looked at this and come up with different answers, but I think it is profoundly important for you to understand that the only judge who has actually examined this with the totality of the circumstances the way it would come in at trial, not in a vacuum in an evidentiary hearing, but specifically with how it fits in the case, was Judge Jones in *Phillips*.

And what Judge Jones said is that, look, you cannot go and throw a cloak of secrecy over something to prevent cross-examination on that.

Mr. North agreed. He said, no, I don't think you can do that. Now he goes on to argue that that's not what happened here, that this was the only time we had this extensive type of MAUDE data analysis, but Judge Jones rejected that, and for good reason, because we do have before and after this extensive MAUDE data analysis, sales analysis, the bench testing.

So it's very important to understand that

Judge Jones, after hearing how this was used in the context of

trial, which is basically the same totality of circumstances

analysis that you will have to conduct in this case, found

that this was part and parcel of the ordinary course of

business for Bard.

Now, we go into, fairly extensively, on some waiver

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analysis. I don't want to take the Court's time with that. I think it's fairly well submitted in the briefs. But what I will say is this idea that Bard has not sought to use this as both sword and shield is, in our view, somewhat of a red herring. Because the issue is not the document itself. The issue is whether Bard is injecting issues in the case that make that document important. They can't hide what they knew and at the same time say that — for example, if you look at its affirmative defenses, there's no less than eight of them that deal with the product safety, efficacy, risk benefit, all of those things the Lehmann report is directly not only relevant to, but establishes what they knew.

And so it is important to understand that they can't have it both ways. They can't come in here and say that this is a safe product, we had no reason to warn, we had no reason to recall, when we know from these documents that it did.

Other than that, I think the issues are fairly well set forth in the brief. I could go on, but I get the sense that you might have some questions for the parties, so I will leave it at that.

But just in closing, I would really commend to your evaluation those documents that I mentioned, and I have a copy of the PowerPoint if the Court would like it, and I can give one to counsel. But it is really important to understand that there is a big dispute in this case. The documents themselves

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show you why we had to have this from Bard's perspective.

Dr. Lehmann told them that they needed it. And that's why we have it.

Independent of any purpose with the legal department, and when you read the cases you will see that you don't just look at one motivation, you look at all of the motives, and if you would have this document anyway, just like in *Ritchie*, where there's the audit report that was required, we submit that this type of material was exactly what Bard was required to do. That's why we have it. And that's why it is not privileged.

THE COURT: Okay. I'll ask my other questions in a minute.

Any reply, Mr. North?

MR. NORTH: Very briefly, Your Honor.

I would just note the plaintiffs focus principally on the MAUDE database analysis. And yes, Dr. Lehmann did propose that back when he was interim medical director, but there's absolutely no evidence that was done.

Then if you look at the contract he entered with the law department, and this is schedule A, and that is Exhibit R to our motion, the MAUDE database is just one of several different tasks the law department asked him to do. They asked him to perform a literature review regarding risks and benefits of filters. They asked him to look at the complaint

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files. They asked him to consult with appropriate experts in surgery, medicine, radiology. They asked him to consider clinical studies that might allow a better assessment of the risk.

And Ms. Passero made it very clear in her testimony the company was receiving adverse event reports of a small number of deaths involving the recovery filter migrating to the heart. They were naturally concerned. They were having lawyers contact them. They were reporting things to their insurance company.

The law department, as lawyers, really didn't know what sort of risk was out there, what were they facing. And so they commissioned Dr. Lehmann to do all these tasks in an assessment of the risk so that they could properly, as Ms. Passero says, advise the senior management and to advise the board of directors as to what sort of litigation risk and company risk they might be facing.

Now, Ms. Passero also testified that when she received the draft, and there was an initial draft of Dr. Lehmann's report before the final report, she was concerned. The report said that further investigation was urgently needed, and Ms. Passero said that she did what she hopes every well-meaning, good-intentioned lawyer in-house does, is when you see something that says there may be a safety issue with your product, she got that report in the

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hands of the people that needed to know, and needed to know how to act upon that report.

But that was not why it was created. That was how it was later used, in part, by the business. And that is why you see the December 9 draft remedial action plan that later became final in January, because she turned it over to the people that she thought had a need to know about a study that said further investigation is urgently needed because of a safety issue.

But again, that's not the test we submit for work product. Whether this was prepared in anticipation of litigation turns on why it was created in the first instance, not how it was later used.

And that's why virtually every court to address this issue, with only one or two exceptions, have found that just because this was later used for business purposes does not negate the fact that it was originally created, and the record's unrefuted, we submit, originally created in anticipation of litigation.

In Nevada, in the *Phillips* case, Magistrate Cobb looked at a lot of these documents; he looked at documents in camera; he did privilege reviews of many of the Lehmann-related documents. And he issued an opinion, my recollection is it's a 60- or 70-page opinion, very detailed, where he, like most of the other judges to consider this,

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found it to indeed be privileged. They are correct that Judge Jones later reversed that decision.

But, again, we believe he, and I say this respectfully, erroneously focused on the later business uses of the report as opposed to why it was created.

And for all those reasons — oh, and lastly,

Your Honor, I want to address the sword and shield argument
they're making. I would suggest or submit that that is not an
appropriate application of the sword and shield doctrine. As
I understand that doctrine, that involves a situation where a
party comes in and wants to use a document or a privileged
material for their benefit, but then to keep the plaintiffs or
the opposing party to use it for their benefit.

There is no evidence and there could be no evidence that we are trying to affirmatively use the Lehmann report or the Lehmann analysis. We are not and never have attempted to use that as a sword. Instead, we have said from the beginning that document is privileged.

Unfortunately, years ago our ESI vendor, despite significant discussions beforehand about the privileged nature of that document, inadvertently produced that document, and we've been fighting a callback battle ever since.

But the fact of the matter is we have not ever affirmatively used that document or attempted to, and therefore we submit that the sword and shield doctrine does

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not apply here.

So, Your Honor, for those reasons and all the reasons we set forth in the brief and for -- based on the testimony that's previously been given, we would ask this Court to grant our motion for protective order. And I stand ready to address any questions that the Court may have.

THE COURT: Okay. Let me ask you a few questions,

Mr. North. I haven't read the documents so this may be

evident when I read them, but the plaintiffs are asserting

that the December 4th draft remedial action plan or remedial

action plan and the January remedial action plan, maybe it was

December 9th and January 4th, and the HHE all quote from the

Lehmann report. Do you agree that those documents quote from

the Lehmann report?

MR. NORTH: Yes, Your Honor, I do.

THE COURT: So I can conclude that from that, I assume, that that report was used by the company in the preparation of the remedial action plan and in the HHE?

MR. NORTH: Yes, Your Honor. Consistent with Ms. Passero's testimony that upon receipt of this disturbing document to her, concerning document, she turned it over to the people she thought needed to act upon it from a business sense.

THE COURT: There's the statement that's quoted, I think three times, in the plaintiffs brief that the Lehmann

report -- that the work of Dr. Lehmann was commissioned by 09:40:46 1 2 senior management to provide an independent analysis of risks. 3 In your reply, which is at Docket 412, on page 7, I 4 think you're saying that you think that the statement that 09:41:15 5 senior management commissioned is wrong. You say, "Thus, the language in the remedial action plan is clearly an error." 6 7 So are you saying that Bard was wrong when it said 8 senior management commissioned the study? 9 MR. NORTH: Your Honor, I'm not sure "wrong" is -really was a very accurate way of saying that it's 09:41:35 10 11 imprecise --12 THE COURT REPORTER: Excuse me, Counsel. shoulder is rubbing against the mic and I can't hear you. 13 14 MR. NORTH: Oh, I'm sorry. THE COURT: Move both mics in front of you. They'll 09:41:41 15 16 bend over. 17 MR. NORTH: Now, if you're talking about people at the division level in Tempe at Bard Peripheral Vascular are 18 performing this -- constructing this remedial action plan, 19 09:42:00 20 they're told that someone in corporate headquarters, in this instance it was Ms. Passero and her boss, the general counsel, 21 22 Judy Reinsdorf, who commissioned this, and they referred to 23 them imprecisely as corporate senior management. So I don't think it's really incorrect as much as it 24 09:42:16 25 is an imprecise reference to someone at corporate headquarters 09:42:20

having commissioned this, as opposed to someone at the division level.

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THE COURT: Well, so for purposes of ruling on this motion, you want me to assume that senior management, as that is typically used, didn't commission the report, and that Bard's public statement to the contrary is wrong?

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MR. NORTH: Right, Your Honor. To that extent, yes. The division people improperly referred — if you interpret senior management to be CEO, COO, people of that ilk, as opposed to the corporate legal department, yes, that's wrong.

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THE COURT: Is there evidence in this record that the people who wrote that statement misunderstood or didn't know who had commissioned the Lehmann analysis?

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MR. NORTH: Not that I'm aware of, Your Honor. But conversely I don't believe there's any identification by them of the people that — and I understand the Court's — the fact that we all think of corporate senior management as being this specific subset, but I would also respectfully submit that in a company that is constructed like Bard, where everyday activities like this are at the division level here in Tempe and there is this corporate headquarters in New Jersey where the COO, CEO, law department, vice presidents of various divisions are, it is, I see it all the time, typical for the people at the division to consider all those folks in

New Jersey corporate management.

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Is there evidence in the record that it 09:44:10 1 2 was those Tempe people who wrote the December 2004 remedial 3 action plan? 4 MR. NORTH: My understanding is that, yes, it is 09:44:26 5 Doug Ulman was the vice president of quality assurance located 6 here in Tempe, and I believe he is the author of that 7 December 9th document, for example. 8 THE COURT: My question, though, was is there 9 evidence of that in this briefing? Can I look somewhere to 09:44:41 10 say this statement was made by people in Tempe and not people 11 in New Jersey? 12 MR. NORTH: Not that I'm aware of, Your Honor. 13 will look for something during the course of the day and mention that, but as I sit here right now, I'm not certain of 14 09:44:58 15 anything. 16 THE COURT: Okay. 17 One of the arguments the plaintiff makes is -- that the plaintiffs make is that there's evidence of several 18 nonlegal uses of the Lehmann report, and there is no evidence 19 in the record of any legal uses of the Lehmann report. 09:45:40 20 21 What is your response to that? 2.2 MR. NORTH: Well, I would hope that the privilege was 23 protected enough that there would not be, Your Honor. 24 Ms. Passero testified that the legal department used it in 09:45:55 25 their assessment of the analysis. There should not be --

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THE COURT: Is that testimony in the record?
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                        MR. NORTH:
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                        THE COURT:
                                    Do you know where that is?
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                        MR. NORTH:
                                    I will get you the citation today, Judge.
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                        THE COURT: Okay.
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                        MR. NORTH:
                                    They used it as a part of their
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               assessment to advise the board of directors, to advise senior
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              management as to the risk that they were facing. You would
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               not expect there to be produced documents in litigation about
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               their assessment of that risk based on this analysis.
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                        THE COURT: Was the Lehmann report attached to the
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               January 4th, 2005, remedial action plan?
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                        MR. NORTH: Yes, Your Honor.
                        THE COURT: And where did that remedial action plan
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               qo?
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                        MR. NORTH: The remedial action plan, as I understand
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               it, is maintained at the division.
                        THE COURT: Was it disseminated outside of the
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               company at all?
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                        MR. NORTH: No. Not until litigation.
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                        THE COURT: Was the remedial action plan given to the
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               FDA?
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                        MR. NORTH: No. It is maintained in the records, as
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               it is required to be by the company, and if the FDA comes for
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              an inspection, they're entitled to see it. But I'm unaware of
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any evidence they came and looked at that document.

THE COURT: So if I understand you correctly, the remedial action plan has been produced in discovery in this litigation and that's how it's part of the litigation, but it wasn't disseminated outside of the company, to your knowledge?

MR. NORTH: Right. That is my understanding.

THE COURT: What about the HHE?

MR. NORTH: The same thing. It's maintained in the company's records. It is not disseminated outside the company. It's — the company is required to maintain those sort of analyses. I'm sure the FDA has the right to inspect them if they come in. I'm unaware of any evidence that they did come in in this instance and look at that particular document.

THE COURT: Plaintiffs assert that the Lehmann report is the only collection of MAUDE data analysis that Bard has produced in any litigation. Do you agree with that?

MR. NORTH: Absolutely not, Your Honor. There are many, many internal evaluations by the quality assurance department over the years looking at MAUDE data. There are spreadsheets, basically on a monthly basis, by the quality assurance department, not only involving the recovery filter, involving later generation filters. Those are the centerpiece of some of the plaintiffs' allegations against us. This is just one use of the MAUDE data. But of course the ones

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performed by the quality assurance department, we would never claim a privilege for because those were not prepared in anticipation of litigation and were prepared as a part of the normal trending done by the quality department.

THE COURT: The -- in arguing about whether or not the plaintiffs have shown a substantial need for this information, you argue that they don't have a substantial need because they've got all the MAUDE data, they can do the same analysis Dr. Lehmann did. In fact, they have had experts in some of the cases that have done just that analysis.

And I understand how that would show that the plaintiffs don't need the Lehmann report to do MAUDE data analysis or to make arguments to the jury about what the MAUDE data analysis shows.

However, it seems to me part of what they're arguing is that there's a different fact they want to prove for which they had a substantial need for the Lehmann report, and that fact is what Bard knew in December of 2004 and January of 2005. And the Lehmann report shows what Bard knew, and no amount of analyzing the MAUDE data by an expert will show what Bard knew.

What is your response to that?

MR. NORTH: They have ample proof of that,

Your Honor. They have the HHE. They have the remedial action

plans where the same points are discussed. But not from the

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privileged document itself in its entirety. They have that evidence. They have, like you said, the underlying data, and they have evidence that Bard was aware of that data from the remedial action plan.

THE COURT: I haven't read them yet, but I think they argue that the remedial action plan and HHE do not quote the negative statements from the Lehmann report that show actual knowledge of those negative facts. Is that --

MR. NORTH: Respectfully --

THE COURT: -- incorrect?

MR. NORTH: -- I do not believe that is correct,
Your Honor. The remedial action plan cites the statistical
findings, you know, conclusions from the Lehmann report in a
very summary fashion, and it also cites the flaws in the
analysis that Dr. Lehmann recognized himself, which is that
there are gross inaccuracies in the MAUDE database, and that
you have to use it for these purposes very skeptically. And
the FDA has said the MAUDE database should not be used for
comparative analysis, in fact, because it is not a reliable
indicator.

But the remedial action plan does show awareness on the part of Bard as to the findings of this flawed analysis as far as comparative rates are concerned.

THE COURT: Okay. I think I covered -- hold on just one minute. Let me look at one other document.

09:54:53 1 Bard never issued a recall of the recovery filter. 2 MR. NORTH: No. Bard did quit selling the product in 3 September of 2005, at the same moment that it introduced the 4 second generation filter called the G2. 09:55:32 5 THE COURT: Ms. Passero said she delivered -- she distributed the Lehmann report to five other employees, but 6 7 the briefing suggests it got into the hands of at least a 8 dozen employees. 9 Is there any evidence as to how it got from the five to the 12? 09:55:50 10 11 MR. NORTH: I don't know that there's evidence 12 presented in the record that you have been given. I think that, if I recall what we've seen over the years, it's like --13 it went to the vice president of quality assurance, 14 Chris Ganser, at the corporate headquarters, who then shared 09:56:06 15 it with the vice president of quality at the division. And it 16 17 was just sort of the natural -- as people looked at it and said we need to act upon this in the quality department, it 18 was -- the pool of people expanded. 19 09:56:23 20 THE COURT: Okay. Thanks. Those are my questions. 21 MR. NORTH: And I will try to see if I can get 22 answers to those two questions while we proceed. 23 THE COURT: Okay. 24 Mr. Clark, a few questions for you. 09:56:35 25 MR. CLARK: Thank you, Your Honor.

THE COURT: Let's talk for a minute about your -- an assertion made in your brief. I'm looking at page 17, and maybe it's elsewhere, but you say -- I'm on -- I'm looking at page 17 starting line 10.

MR. CLARK: I didn't hear you, Your Honor. You said line 10?

THE COURT: Line 10.

You say, "Bard had an independent responsibility to conduct the very analysis it commissioned Dr. Lehmann to perform." And then you give CFR cite.

And then you say, "And the report contains the very analysis he had provided to Bard during the spring and summer of 2004," and you give no citation to the record.

What evidence is there that the Lehmann report contained the very analysis that Lehmann had provided to Bard during the spring and summer of 2004?

MR. CLARK: Your Honor, I apologize. We have the March 2004 HHE, which — and you have to understand that as more complaints are received, this data is changing, but the framework of this analysis, this idea that it surfaced for the first time in the Lehmann report is belied by an examination of those HHE documents.

So we have the March 2004 HHE, which is an exhibit to our brief, and I apologize, I don't have it handy. We have the April HHE, which was attached to the defendants' reply

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memorandum. We also have analysis that is contained in the -Dr. Lehmann's response to the crisis communication team that
talks about the bench testing that he examined. And finally,
we have the July 2004 HHE that is authored by Dr. Ciavarella,
which relies in part on the information provided by
Dr. Lehmann.

So we have -- and when you look at that, you see the same type of information. MAUDE data analysis, sales figures analysis. And then you see percentages, calculations, rates that are being done. So it's the same framework. It's just being amplified as more complaints are being received.

Mr. North said there's also a literature review.

Well, if you look at the authorities that are cited in each of those HHEs, you will see tons of articles and literature review. In fact, there's in excess of 100 just to the March one alone.

So, again, there is nothing unique about that December report other than it is the collection of all of that information that is brought current as of that time.

And you raised a very good point, that is the only place where we have all of that data together to show what Bard knew, and that is important because when you look at the remedial action plan, you have to examine — that is Bard's characterization of that report, what it did and what it didn't do. But we are entitled to look at whether Bard's

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characterization of that is fair, specifically with respect to conclusions drawn about bariatric patients, trauma patients, which Dr. Lehmann said, hey, we just can't do that yet because it's going to take too long.

A big claim in here is the failure of Bard to take this off the market earlier or recall it. What the conclusion in the remedial action plan was is, you know what, the data's a little squishy. Let's hold off on this until G2 is ready.

So these are all things the plaintiffs should be permitted to explore, not only in discovery, but also to talk to the jury to about --

THE COURT: All right. Give me -- you shifted to the substantial need argument just then.

MR. CLARK: My apologies.

THE COURT: No, that's all right, because I wanted to talk about it.

Everything you just said, that is, your ability to argue to the jury that Bard's characterization to the FDA was not fair or was not accurate, or the HHE was not fair or was not accurate, you can do that through your own expert. You can put an expert on the stand that says everything Bard says here about the data is wrong and it's misleading, and you can explain why.

So I have trouble with the notion that that kind of an argument creates substantial need for you to get this

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report.

MR. CLARK: The difference between presenting a paid expert who is retained to come in here and explain the work they've done at the expense of plaintiffs to collect all this data, to show the exact same information, it's just a -- it's a magnitude of different from a credibility perspective. If the jury, the way that they examine experts, is they're paid to do what they're going to do, and both sides have them.

But when you have the person that was the medical director of Bard, who then later continued to consult with Bard, and who, in that capacity, told Bard what they did or didn't do or what they should do, that is an order of magnitude different than what plaintiffs can do with -- it's rubbing two sticks together as opposed to using a blowtorch.

THE COURT: Are you aware of any case, Mr. Clark, which has ever held that a party can show substantial need and get work product because the work product will allow it to make a point more credibly than it can make through its own experts and witnesses?

MR. CLARK: No, Your Honor, I'm not. But the caveat is that where the lack of that work product creates a gap that can only be filled with that work product, such as we believe is the case here, then there is that substantial need.

THE COURT: What's the gap?

MR. CLARK: The gap is what Bard knew from its own

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personnel. These are not paid individuals. This is people who have been affiliated and have studied this all for months and months with the company.

THE COURT: Well, you make a pretty detailed argument in your brief that Lehmann knew in the first half of 2004 that this data was problematic, that he was saying to the crisis team, we need to downplay this, that our response should be something like good products, severe event, unfortunate outcome, deep remorse.

You make a pretty detailed argument that Lehmann was spinning this, that he knew it was worse than he was telling the company to portray it. Don't you have evidence from which you can make the very argument you just said you need this report to make?

MR. CLARK: We have evidence of what he is saying up until that point. But Mr. North is a great lawyer, and what he will come up and say is, well, he's saying we still need additional information, we still need to collect more studies, we need to do this work, which he has now done, but now we don't get to say that that work was ever done and it was favorable to plaintiffs' position. So that's the gap. We can take it up to there, but then we have a gap from that point forward.

THE COURT: Let me just ask you about one sentence that is on page 28 of your memorandum, which is Docket 379.

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This is where you're making the substantial need argument. I'm looking at -- beginning on line 12, you say, "But plaintiff should not be required to present the evidence in this cumbersome fashion and incur the expense and delay associated with hiring an independent expert simply to show what Bard knew as of December 2004 and communicated to several high-ranking officials in its corporation."

What it seems to me you're arguing there is that it would be undue hardship for this very experienced, well funded, well organized plaintiffs' team in this case to have to hire an expert on this point.

MR. CLARK: Your Honor, I think to your credit earlier — to your question earlier, is there an authority that would say that presenting it in a slightly better way or cheaper way, I'm not aware of authority that says that. To me it makes very practical sense, but it — when we're looking at substantial need, I think we need to focus on the gap that we've discussed.

THE COURT: Well, but are you arguing that it's an undue hardship for you to have to get an expert on these points and it will take too long and cost too much? In order, you say in this sentence, to show what Bard knew as of December 2004? That implies you could get an expert to do it, it's just going to take too long and cost too much.

MR. CLARK: I would concede that the plaintiffs could

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hire an expert to do that type of analysis. But what I would maintain is the -- what I discussed before, the difference between an expert who was paid by plaintiffs to do that versus the report Bard itself commissioned to do that analysis, which, again, as we've maintained, was for the purpose of complying with its regulatory and manufacturing responsibilities.

THE COURT: Okay. You argue a number of places in your brief that Lehmann was doing the kind of MAUDE database analysis that Bard was required to do in any event.

Can you point me to a specific statute or regulation that says Bard was required to do MAUDE database analysis?

MR. CLARK: Your Honor, off the top of my head, no. But I'd be happy to try to get you a cite in a moment.

What I can point you to is Dr. Ciavarella's testimony as the medical directer of Bard -- of Bard, where he says that that is absolutely incumbent upon the manufacturer. There are regulations with respect to complaint analysis, that type of thing. But with respect to specifically the MAUDE data, I will have to get back to you on that federal regulation citation.

THE COURT: Okay. Maybe you can look at that while we're going through other matters. I would be interested in that cite.

And I understand your point about what Mr. Ciavarella

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says in Exhibit 5.

You argue in your brief and you argued a moment ago that you presented evidence of how the report was used for various business purposes, but there is no evidence of how it was used for legal purposes.

I've never heard it suggested that for a party to show a document is work product, they not only have to show it was created in anticipation of litigation, they have to then show it was used in litigation, and disclose what their attorneys did with it. That's a new idea to me.

Is that reflected in any case?

MR. CLARK: Your Honor, I'm not suggesting that there has to be a full disclosure of the exact use, mental impressions, and opening the door to attorney-client and work product work that flows from that.

But what I am suggesting is we have a very vague statement from Ms. Passero that this is why she commissioned it. She didn't know whether it was necessary for any other purposes, but this is why she did it, and here's what she did with it. We don't have any statements from anybody else about, yes, I received this. The only people who we do have evidence from about what they did with that report is Mr.—Dr. Ciavarella, who says, I got the report. I didn't — I wasn't told there were any restrictions on it, I wasn't told that this was a confidential document, and I was allowed to

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use it as I saw fit in performance of my work as medical director for Bard.

So all I'm suggesting, Your Honor, is that there is a significant gap in the evidence there. We have very kind of spendthrift allegations from Ms. Passero versus voluminous documentary and testimonial evidence from Bard's own witnesses.

THE COURT: All right.

One of the points you made in your brief is that if I'm inclined to rule against you, I should hold off and allow additional discovery.

I'm troubled by the notion that this very issue has been litigated 15 times in 15 different cases by very capable plaintiffs' lawyers and you need more discovery? Could you explain that?

MR. CLARK: Sure. And I think Your Honor identified a few things that would be fertile territory for discovery because we still have gaps. And despite the fact this has been litigated a number of times before, it's never been litigated in an MDL context where the parties are representing interests other than the specific individuals in these cases, so that's a factor.

But you mentioned earlier that has there been any discovery about what these people knew or should have known when they were writing, but this report was commissioned by

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corporate senior management. Well, you know, there was a draft report on that that went up to the VP of quality assurance, and there was never a correction there saying, hey, you know what, let's put "law department" there, it's not corporate senior management.

That corporate senior management dialogue appears in no less than three documents. So, you know, I think certainly that is something that we suggest is very consistent with what we're saying, which is that this --

THE COURT: But you've known about that all along.

And you're good lawyers. You surely have thought about that.

Why hadn't you previously sought discovery on that?

MR. CLARK: I can't speak for what was done in individual cases other than we have other considerations that are happening with respect to those specific parties. But here it is front and center in a case that may affect hundreds if not thousands of cases.

So the suggestion here is that limited discovery to identify some of the issues that the Court has just addressed, as well as things like Dr. Lehmann's time sheets.

I also would mention that, you know, as we'll talk about later today, there are still some issues with the privilege log, still some issues with ESI and protocol. So I can't stand here and represent that I am supremely confident that all of the information that would be relevant to this has

been produced in the case.

So I think to the extent the Court has any abiding concerns about whether this is work product, then some limited targeted discovery that can probably be conducted in the course of a couple weeks or a month would be appropriate.

THE COURT: All right. Let me ask you this, and then I may have just one or two other questions. It concerns the effect of my ruling on this issue.

Do you agree that in this MDL I am to apply Ninth Circuit law?

MR. CLARK: Yes.

THE COURT: And do you agree that my decision based on Ninth Circuit law will apply even to cases that came from outside of the Ninth Circuit?

MR. CLARK: Your Honor --

THE COURT: I'm not talking about the old ones where it was already decided. I'm talking about the new cases.

MR. CLARK: Your Honor, I think your decision will become law of this case. And so to the extent there would be an argument under the forum jurisdiction law for whatever changing the law of the case, I don't think the parties would be precluded from that, but I think in the normal course of things, your decision will be the law of the case for these cases.

THE COURT: Do you have any evidence, Mr. Clark, that

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Dr. Lehmann continued to work for Bard between May of 2004 and November of 2004?

MR. CLARK: Your Honor, Dr. Ciavarella says in his deposition that he would continue to work with Dr. Lehmann as he was getting his feet wet and learning the job. He also talked about utilizing Lehmann's work in his HHEs, which I assume would include the July 2004 HHE. He said in his deposition that he would have meetings with Dr. Lehmann from time to time.

So the dates are not specific there, so I don't want to misrepresent anything to the Court, but certainly given the fact that Mr. Ciavarella assumed his responsibilities, I believe, in late May 2004 and continued to have meetings with Dr. Lehmann, who resides on the east coast, I think that is a very fair inference from the evidence we have.

THE COURT: Okay. Thanks. That covers the questions I had.

Was there any final point you wanted to make?

MR. CLARK: Your Honor, I think you asked a lot of astute questions about what evidence we do and don't have.

And in particular, the fact that this report was attached to documents that are retained at Bard, but there's no evidence that that RAP, for example, is restricted, that people can't go and look at that at Bard. That is not in the record before the Court. It is in the record that it was attached to the

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RAP, so --

You know, when parties do things that substantially increase the risk of the document becoming public or being disseminated beyond the scope of intended recipients, that can be a waiver.

So it is Bard's burden to establish here that this is privilege in the first instance, and also that reasonable measures were taken to maintain that privilege. And I don't think that's been carried here, Your Honor.

Thank you.

THE COURT: Okay. Thanks.

Any final points, Mr. North?

MR. NORTH: If I could just give you a couple record cites, Your Honor, on questions you had raised.

THE COURT: Sure.

MR. NORTH: As far as the question of any evidence in the record that the drafters of the remedial action plan were at the division level, I would draw the Court's attention to document, it's in the docket as 306-1, and if you look at page 42. This is the January 4 remedial action plan. This has the division product assessment team showing that they were Tempe people that were preparing that final remedial action plan.

In turn, on the draft of the remedial action plan that was prepared or -- in January -- I mean in December of 2004, if you look at docket number Document 379-1, page 22 of

173, it is the e-mail transmitting that draft. It is from 10:16:08 1 2 Mr. Doug Ulman. His e-mail address shows he's from Tempe. 3 And on the previous document I cited, it shows that he was part of that division product assessment team as the vice 5 president of quality. 10:16:27 Lastly, Your Honor, I would cite again to the January 6 7 2005 remedial action plan, Document 306-1. 8 THE COURT: Hold on just a minute. 9 Okay. Give me the last cite again. Start over. 10:16:49 10 MR. NORTH: The last cite I would give the Court is 11 Document 306-1. That's the January 2005 remedial action plan 12 again. Page 44 of 161 demonstrates the fact that the remedial action plan shows Bard's notice of the analysis prepared by 13 Dr. Lehmann, because it has a number of citations to that 14 10:17:15 15 data. THE COURT: Explain the relevancy of that last cite. 16 17 MR. NORTH: I'm sorry, what? THE COURT: Explain the relevancy of the last cite, 18 that the remedial action plan shows Bard's notice of documents 19 10:17:28 20 and data. 21 MR. NORTH: In the discussions and questions you 22 asked about substantial need. You asked, well, isn't the 23 Lehmann report itself necessary to show Bard's knowledge 24 during that period. And you asked whether the remedial action 10:17:42 25 plan and the health hazard evaluation themselves shows Bard's

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notice of the results of the Lehmann analysis. And this demonstrates that they do.

THE COURT: Well, what results does it show Bard knew? Does it -- does this cite show Bard knew all of the negative statements that are in the Lehmann report? I assume it doesn't repeat them.

MR. NORTH: It shows Bard was aware of a number of the central points. It's not a verbatim quotation of the report, but I think it refutes any suggestion by the plaintiffs that the later documents don't show the negative findings from the Lehmann report.

THE COURT: Okay.

MR. NORTH: Thank you, Your Honor.

THE COURT: All right.

I will take the Lehmann issue under advisement, and I will get you a decision on that in the next few weeks. And in the process, I'll consider these questions of whether more discovery is needed or another evidentiary hearing is needed or whether I can rule now.

We're going to take a break at 10:30, but what I would like to do is shift gears and go to more general case management matters. Let's do a few housekeeping things before we jump into your joint report. Just some general questions that I have for counsel. Let's start with plaintiffs' counsel.

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When we were here back in October, you estimated that this case could grow to 1,000 or even 2,000 cases. As of yesterday we had 177.

What are you hearing? What's the sense you're getting out in the field as to how many cases are being collected and how many are coming?

MR. BOATMAN: Your Honor, it's very imprecise.

There's several things that are going on. One is that there are people within our group that we know have several hundred cases that have not filed. I'm not sure why other than it's only been a few weeks since the short form was up, and it may be there's people hoping that the case settles and they don't have to ever file. But there's several hundred that we are told that people have that have not yet been filed. Others intend to file, they just haven't done so yet.

There's another group, and I don't know this number other than the people we've met with the last couple days in preparation for this hearing, there's still, as Mr. North mentioned at the last hearing, this has been — there's a lot of TV ads running. It's, I think, still the biggest ad running for legal product defect cases.

There are people that have thousands of responses to those ads, but do not yet know exactly whether -- most people don't know if they have a Bard or a Cook or some other device.

So we have those that are people who know they have a

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case and they haven't filed yet that we know are several hundred. And we have hundreds, if not thousands, more of cases that people have approached attorneys or hired attorneys that the attorneys do not yet know if they're a Bard Case.

THE COURT: Is there a reason that I should try to control that in some way? Should I set a date by which existing cases have to be brought here?

Well, or a related question, it's a different question but related. I was asked by the clerk's office yesterday, is there going to be a cutoff date? Is there going to be a point in time in the future where we say no more cases in this MDL? I'm interested in your thoughts on those issues.

MR. BOATMAN: Well, I think it's going to be difficult, certainly, to have anything in the very near future on that point because it can be very difficult with some of these cases. It can take a few months to get the medical records to allow you to determine what filter was in a patient.

And I'm not sure how we would ever know whether an attorney — if an attorney gets a case, say you make the cutoff in August and a new case comes in, somebody's injured or killed, and they get the case in September, how would we ever know whether that person had the case and chose not to file it as opposed to a new person being injured or killed and that coming to light after whatever deadline the Court might

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I agree with you, I think it makes sense and, in fact, Mr. Lopez and I made a push to try to get people to get their cases filed, and I think quite a few were filed in the last few days. And I think that -- I know that several people did not quite make the deadline; we hoped to have them on file before today. And there's people that have told me, we're sorry, we were doing our best efforts, but they didn't get them filed yet. I think there's going to be a substantial influx in the next couple of weeks.

THE COURT: All right. Any thought -- thank you.

Any thoughts from defense counsel on this point?

MR. NORTH: We're sort of at the mercy of what comes
in, Your Honor. We do try to monitor attorney advertising,
and, interestingly, it appears to be declining. We'll see if
that's a long-term trend or not.

THE COURT: Okay. From plaintiffs' counsel, any thoughts about how -- well, actually from both sides, how the master complaint process is working, short-form complaints?

Any concerns?

MR. BOATMAN: Your Honor, I think it's working real well with -- we made one mistake or something we'd like to amend, and that is to add a request for a jury trial as part of the short-form complaint so that the parties don't have to make a separate filing requesting that after the filing. And

that's something that defense counsel agrees with, as well. 10:24:22 1 2 So with the Court's permission, we hope to take care of that. 3 THE COURT: Well, so how do we take care of that? What is it that I need to do on that? 10:24:38 5 MR. CLARK: Your Honor, I can address that. We have proposed --6 7 THE COURT: Let's have you come back to a mic because 8 folks on the phone won't be able to hear you, Mr. Clark. 9 MR. CLARK: We've proposed an amended short-form complaint that the defendant has approved, so we can circulate 10:24:51 10 11 that. The only question, I guess, in my mind is do we also 12 need to amend Case Management Order 4 to reflect that -- the use of the amended complaint. So I think we probably ought to 13 do that and submit a proposed revised case management order 14 10:25:10 15 along those lines for the Court to review. 16 THE COURT: Well, yeah, since we have a master short-form complaint in Case Management Order 4, it seems to 17 me we need to correct that or amend it. So what I would ask 18 you to do is get me a stipulated order amending it and 19 10:25:30 20 attaching the new short-form complaint, and let's do that sooner rather than later so that we don't create this jury 21 22 issue in more cases than we need to. 23 MR. CLARK: We'll take care of that next week, 24 Your Honor. 10:25:41 25 THE COURT: Okay.

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This is a minor matter, but both the master complaint and the master answer in the docket are not in text-searchable form as is required by our CM/ECF system. So, for example, yesterday when I went to the master complaint to look up what it said about a particular issue you were briefing, I couldn't search it.

So what we're going to do -- and it's true of the answer, as well. What we're going to do is ask you to get a text-searchable version to --

Nancy, are we giving it to you? Send it to Nancy Outley by e-mail? Does that work, Nancy?

Okay. Each of you send her a text-searchable version of exactly the same master complaint and master answer that are in the docket, and we're going to simply replace the documents in the docket at their current location with the text-searchable form. So it won't become a new docket entry, but then folks can search those long documents when they need to find what was alleged or what was denied.

Did defendants have any thoughts on how the process is working and whether there's anything other than this jury trial issue we need to fix?

MR. NORTH: Your Honor, we've consented to their amendment for that.

We've just recognized an anomaly ourselves from our standpoint, which is that we file just notices of appearance

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to constitute the answer for short-form complaints in response. The order only applies that procedure to short-form complaints, and we're getting a handful of complaints filed in other districts and then transferred here. So the way the order reads, we still have to file formal answers in that.

We just sort of realized that anomaly, and we are trying to figure out if it would make sense to come back to the Court to propose that we just adopt the master answer in all cases, regardless of whether they're directly filed here or filed elsewhere. And we haven't really wrestled that one to the ground yet.

THE COURT: Well, would there be a problem -- would there be a problem with me saying in this revised case management order that's going to address the jury trial issue that defendants are authorized in any case where an actual complaint is filed to file a one-page answer that incorporates by reference the master answer? So then all you have to do is file that document, you don't have to do anything -- you can say we incorporate the master -- the master answer pursuant to order X in the MDL, and that would seem to solve the problem.

MR. NORTH: I think that would be wonderful if the plaintiffs would consent. It would save a lot of paper or electronic data.

THE COURT: What do you think?

MR. BOATMAN: That's fine with us.

10:28:57 1 THE COURT: Pardon? 2 MR. BOATMAN: That's fine with us, Your Honor. 3 THE COURT: Okay. So why don't you include that in 4 the stipulated order you're going to get to me, and we'll take 5 care of that problem, as well. 10:29:04 I want to turn next to what's in your joint report, 6 7 but we're at about 10:30. Let's break until 10:45, and we'll resume at that point. 8 9 (Recess taken from 10:29 recess to 10:47.) THE COURT: All right. Counsel, let me mention 10:47:27 10 11 something Nancy mentioned to me during the break. You 12 probably know this, or most of you do, but she wanted me to point out because of the question that was asked that on the 13 court website, you can go to the Cases of Interest location 14 and there is a section for this case, and on it are all of the 10:47:44 15 case management orders, the short-form complaint. All of that 16 17 stuff is available on the website. So that will be helpful, hopefully, to folks who want to learn more about the case. 18 19 Okay. Let's talk about --10:48:05 20 MR. CLARK: Your Honor. 21 THE COURT: Yes? 22 MR. CLARK: Just a follow-up. You had asked me for a 23 citation. 24 THE COURT: Sure. 10:48:11 25 MR. CLARK: Mind if I provide that to the Court now?

10:48:13 1 THE COURT: Yeah, that's fine. 2 MR. CLARK: As far as the regulations, let me refer 3 the Court to 21 CFR 820.22. 4 THE COURT: Just a second. 21 CFR 820.22? 10:48:33 5 MR. CLARK: .22, that's correct, Your Honor, which talks about quality audits and imposes upon manufacturers a 6 7 responsibility to establish procedures for doing that. 8 And then if you compare that with Exhibits 4, 5, 6, 9 1, 13, and 19 of plaintiffs' brief, you will see that the way that Bard has chosen to do that is to in part evaluate the 10:48:54 10 11 MAUDE database. All of the health hazard evaluations have 12 some qualitative analysis of MAUDE as part of that responsibility when it investigates complaints. 13 Thank you. 14 10:49:11 15 THE COURT: Thanks. Let's turn to the joint --16 17 (Loud noise.) 18 THE COURT: I'm okay. Let's turn to the joint report and talk through 19 10:49:42 20 issues in the joint report. I think your proposal of distinguishing between what you call first track cases and 21 2.2 second track cases makes sense. 23 You didn't specifically identify the first track 24 cases in your joint report, you referred me to some other 10:50:10 25 document that I didn't have time to look at, but I think I

should be very clear just as to what the first track cases 10:50:13 1 2 are. 3 Are those the same cases that we called out in the 4 previous case management order? I can't remember if there 10:50:22 were 13 of them or something like that? That's the same group of cases? 6 7 MR. NORTH: Yes, Your Honor. It's in the master 8 complaint case management order. 9 THE COURT: Okay. 10:50:40 10 The schedule you proposed is on page 3 of your joint report, which is at Docket 451, and it would have us getting 11 12 to the close of expert discovery on November 4th of 2016. 13 Here's the question that I have about this. The two areas of discovery that you identified for these older, well 14 developed, mature cases are the FDA warning case and the 10:51:16 15 16 Kay Fuller allegations. Those are the only two areas of 17 discovery that are addressed. Is it the view of the parties that those are the only 18 two areas that need to be the subject of discovery on these 19 10:51:34 20 older cases? Is that a correct understanding? 21 MR. LOPEZ: Well --22 THE COURT: Pull the mic over, would you, Mr. Lopez. 23 MR. LOPEZ: I can come --24 THE COURT: You're okay if you just kind of slide the 10:51:45 25 mic over. Folks on the phone don't hear unless you're talking 10:51:48 1 pretty close to a mic. 2 3 4 10:52:02 6 open. 7 8 9 10:52:19 10 11 12 13 14 10:52:40 15 and set for trial? 16 17 additional discovery we think is warranted. 18 19 10:52:53 20 were. Were there 13 cases? 21 22 MR. LOPEZ: 13. 13. 23 24 10:53:05 25

MR. LOPEZ: I would say as to the cases where discovery's closed as they existed prior to the transfer to the MDL, where it gets a little dicey, Your Honor, the -- I counted about five or six of these where discovery was still So the issue is not whether or not they should be

able to do more discovery other than the two areas you talked about, but can those cases -- if there's discovery going on in phase two, would those cases automatically have an opportunity to use that discovery in their cases because discovery is still open? Or maybe put it a different way, should all those cases still have the benefit of that discovery if that discovery occurs prior to those cases actually being remanded

But I think the answer to your first question, specifically for those 13 cases, that's the focus of the

THE COURT: Well, am I correct, Mr. Lopez, in understanding that of these -- I can't remember how many there

THE COURT: Of those 13 cases, there are four or five where discovery was still open when the MDL was formed?

MR. LOPEZ: There are -- if I could just highlight

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them.

About that, Your Honor. Four or five. Five.

THE COURT: Are you proposing that in the first track schedule for these 13 cases that you do additional discovery besides the Fuller and the FDA warning letter issues?

MR. LOPEZ: Are you talking about all 13, Your Honor, or the ones where discovery's been closed?

THE COURT: Well, all 13. This is now an MDL, so it seems to me what we won't be doing in this MDL is discovery for a specific case. And so if I'm going to say we've got first track and we've got second track cases, then the question is not what a particular case in the first track needs, but what's the discovery we're going to do on that track.

MR. LOPEZ: I understand. And I think this: As to all 13, as long as we complete the discovery that relates to the warning letter and the Kay Fuller issue, those 13 cases will be -- discovery will be closed and ready for whatever the next phase happens to be in those cases. Some of them, experts have already been deposed, exchanged Rule 26. The Tillman case, we're just waiting for motions in limine.

Others, experts are pending. So once that's completed, those 13 cases can then go to whatever the next phase would have been had discovery been closed.

THE COURT: Well, that gets to my next question,

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which is your first track schedule calls for a close of phase two discovery on July 1st, and then it calls for plaintiffs' supplemental expert reports on July 31st.

Is your thought that those supplemental reports would be limited to what is learned in the Fuller and the FDA warning letter discovery? Or is it something broader that you have in mind?

MR. LOPEZ: You know, I mean, that's like the

Fuller -- or especially the warning letter issue, you know,
when you peel away another layer, you're getting to areas that
might, you know, overlap into discovery that's been taken.

So -- you know, I think the bottom line for those cases are,
Your Honor, once that discovery has been completed, whatever
the Court designates as discovery for phase -- for that phase
of this MDL, those 13 cases are willing to accept that as a
discovery in their case, and then to -- you know -- then we
have to talk about, you know, which ones you remand first, do
you remand them all at the same time, and what do we do with
the cases where there's not been Rule 26 reports and expert
exchanges.

THE COURT: Well, that was my next question, you're anticipating them well, which is I'm assuming some of these 13 cases, if discovery isn't finished, don't have expert reports yet?

MR. LOPEZ: That's true.

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THE COURT: One of the things we're hopefully going to accomplish in this MDL is expert reports, expert depositions, *Daubert* motions. On common issues.

So my question was going to be, if the first track has in it, let's say, five cases where no expert disclosures are done, it seems to me that for those cases, you need more than a supplemental expert report.

MR. LOPEZ: Yes.

THE COURT: You need an expert report, and presumably it's the same expert report that's going to be in the second track cases.

So one of the issues I've been having is does it make sense to divide these up if, in fact, there are things that need to be done in some of the first track cases that are going to be done in the second track?

MR. LOPEZ: Well, you know, it's a flaw that I recognized for the first time when I looked at the schedule, because you can't supplement a report that doesn't exist. So we're dealing with that. And the Court has recognized that. So I think you're correct, I think we need to phase those. It could be that some of those 13 just spill back into the MDL as part of the bellwether process, or we can have a separate discussion about maybe having that — those be expedited somewhere between the ones that are more ready for remand and the true bellwether process that we're going to have in the

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MDL. It's something I think the parties should have, you know, obviously thought through and discussed before we got here. But I noticed that today in looking at this chart.

THE COURT: Well, I'm assuming that before we pick a bellwether trial, from either the first or the second track, we will have to be at a point in this MDL where experts have been disclosed, experts have been deposed, and Daubert motions have been resolved. On the common experts. Because those will have to have been done in any case we're going to take to trial as a bellwether; right?

MR. LOPEZ: If -- if you're talking about bellwether cases that will not be remanded as a -- this is a simple remand case --

THE COURT: I'm talking about bellwether cases, which I understand to be --

MR. LOPEZ: Got to go through all of that, yes, sir.

THE COURT: So here's my question, and I don't know if this is right, but I'm interested in your thoughts. Does it make sense to have a track one -- a first track and a second track? Would it be better to say we've got one track, we're going to move ahead with all of these cases, but if there are among these 13 cases, cases where essentially everything is done and that are ready for remand, then the parties can stipulate to a remand? And we'll send those back whenever they're ready. But why create a second track for

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them, or I should say a first track for them, if some of the cases in that first track have to do the same work as everything in the second track?

MR. LOPEZ: Yeah, I mean, the practicability of that is, you know, obvious. I mean, I think that that's certainly something, as far as all 13 cases that we're talking about from the plaintiffs' perspective, would certainly be acceptable to us, and especially leaving open the idea that we can even remand these — some of these cases because of their readiness even prior to a formal bellwether process that we might set up for new cases or cases that weren't as ready as those maybe three, four, or five cases.

MR. STOLLER: I'm sorry, Your Honor, what I was thinking is the only issue is as to those more advanced cases. We're going to want to treat them a bit differently, for example, where they've been through everything, expert disclosures have been done, and really the only things remaining on them are these two issues. And to the extent that you would supplement your expert issues or your expert reports based on the FDA warning issues and the Kay Fuller issues, if that's really all that remains in those cases, having them sort of fall into the general track where expert disclosure isn't later doesn't make a lot of sense. We may need to have some special provisions for those cases so that we can, in fact, send them out earlier.

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The other option is that you don't build that -- the expert stuff for those cases into the MDL, and that gets handled on remand. I mean, there's -- but either way, they can't be tied to an expert -- you wouldn't want to tie them to a later expert disclosure that's common for all the other cases when essentially, if we do the discovery on the two issues and they're basically done, then they would be just sitting there waiting for something to happen.

THE COURT: Thoughts from defense counsel on this?

MR. NORTH: Your Honor, I think what the Court said makes a lot of sense. My concern, though, is that I've got a chart here I'm looking at of the 13 cases we've previously identified as advanced or almost trial ready. And if I'm reading this correctly, experts have been designated in 12 of the 13. And in the 13th one, the defense designated its experts and the plaintiff, which does not involve any of the attorneys here, apparently missed the deadline.

So experts have essentially been designated in all 13 of those cases. In a small number of them, maybe four or five, there are discrete parts of discovery that still remain. Like two or three of them, not quite all of the experts have been deposed that need to be. There's one or two cases where, by agreement or because of scheduling problems, the parties have agreed to still do a treating physician who could not be scheduled.

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But expert disclosure, that train is way down the track. I'm not averse and I don't think Bard's averse to what the Court's proposing, but I am concerned that the plaintiffs in these 13 cases not get a complete do-over given the fact we're that far along.

THE COURT: Well, what if we were to do this: what if we were to set up one track for the MDL with a schedule something like your second track schedule, but my order establishing this would instruct that the parties, over the course of the next month, need to sit down and talk through these 13 cases and reach agreement on what is done and finished and won't be disturbed in those 13 cases, what more needs to be done in those 13 cases. And on the basis of that, you may decide some cases are ready for remand or you may decide we need to keep them here a few months to do something else. But the point of this discussion and stipulation would be to look at those cases specifically and decide what else do we need to do and how can we most quickly do it.

And if you can reach agreement on that, you can submit a stipulated order. If you disagree, I can make the decision. But that way, we can treat them differently than the rest of the MDL, but we don't need to set up a separate track for them, particularly when they themselves are in different stages of completion and they may not all need what would be on that other track.

MR. NORTH: I think that makes perfect sense, Your Honor.

THE COURT: Mr. Lopez.

MR. LOPEZ: I agree with all of it. My only comment would be if your scheduling order could at least incorporate a time frame within which we should focus our attention on the warning letter and the Kay Fuller issue so that that doesn't get — so if we just sit down and agree that this is going to be a nine-month discovery, I'd hate to see those two issues be put off to months eight and nine, because those two discovery issues could — will obviously have an effect on our discussion about the 13.

THE COURT: I think that's a good point. If it is the case that some portion of these 13 only need the Fuller and the FDA warning letter discovery, let's get that done sooner rather than later. So when we get to those subjects, let's -- depending on how I come out on what discovery is needed, let's talk about what the schedule within a schedule ought to be for getting that discovery done.

But what that means is that instead of -- instead of setting two tracks, we'll simply do a phase two scheduling order for the entire MDL with the caveat that these 13 are going to be discussed separately and dealt with separately.

And I'm assuming it's the parties' view that that schedule should then be the schedule on page 4 of Docket 451;

11:06:20 1 is that right? 2 MR. LOPEZ: That's right, Your Honor. 3 THE COURT: In the second bullet in that schedule, 4 you have October 28th as the close of phase two discovery 11:06:41 5 regarding general issues. Do you mean MDL issues? MR. BOATMAN: Yes, Your Honor. 6 7 MR. LOPEZ: Or maybe non-case-specific issues. 8 MR. NORTH: That's probably a better way of putting 9 it, non case specific, Your Honor. 11:06:53 10 Mr. Stoller and Mr. Lopez and Mr. Boatman and I met 11 about a week ago and talked about proposing to the Court a 12 specific bellwether process for -- to work up in some 13 individual cases, and as a part of that, there might be 14 different discovery deadlines for plaintiffs' depositions, 11:07:10 15 treating physicians. But we're talking about non case 16 specific. 17 THE COURT: Okay. I'm assuming it's the same thing for the expert 18 discovery. When you talk about common-issue expert, you're 19 11:07:24 20 talking about the non-case-specific experts? 21 MR. LOPEZ: We could have called that generic-issue 22 reports. 23 THE COURT: Okay. 24 Let me ask you a question on your proposed expert --11:08:15 25 well, you call it expert discovery. It's May 19th of next

11:08:21 1 year. You say common -- close of common issue expert 2 discovery. Do you mean depositions? Everything other than 3 depositions should be finished with the reports. 4 MR. NORTH: Right. 11:08:32 5 THE COURT: Everybody in agreement on that? 6 MR. STOLLER: Well, I assume we'll exchange 7 documents, but beyond --8 THE COURT: As part of depositions. 9 MR. NORTH: Yeah. 11:08:40 10 THE COURT: I mean, everything the expert can use in 11 terms of a document should be in its report. You're talking 12 about --13 MR. STOLLER: His underlying file, his notes. THE COURT: Yeah, what -- sometimes parties subpoena 14 the other side's expert when they set a deposition. That's 11:08:53 15 what you're including, right, Mr. Stoller? 16 MR. STOLLER: Correct. 17 THE COURT: I'm going to call it depositions because 18 my assumption is you're getting documents relevant to the 19 11:09:06 20 deposition when you're deposing an expert. 21 But here's my question. If we're finishing rebuttal 22 reports on March 3rd, do we really need two and a half months 23 to depose the experts? It seems to me what we could do is 24 make sure that when we produce the plaintiffs' reports in 11:09:26 25 December and the defendants' reports in February, you also

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agree upon deposition dates, get them on the experts' calendars so that you can march through them in a couple-of-week period, and not stretch it out over two and a half months. I'm assuming we might have eight or ten common experts in the case? Maybe 12?

MR. STOLLER: Maybe more, Your Honor. And that was sort of the thought here.

THE COURT: Even if we have 12 or 15, I guess -- I was in a case once where the judge said, and it worked really well, reserve a conference room for three weeks at the Biltmore Hotel. When you produce an expert report, put the expert on the schedule for that three weeks, and this will start two weeks after rebuttals. And you'll all come to Phoenix and you'll all plow through all of the expert depositions in one straight shot and save a lot of travel costs, save a lot of time. I don't know if that's a good idea here or not, but that's what I'm asking.

MR. STOLLER: Well, as always, we'll do whatever you want us to do --

THE COURT: I know that.

MR. STOLLER: It's possible. The concern is really one of if we have ten to 12 experts, is the ability to digest the materials and actually take a reasonable deposition rather than having people sitting in a room, turning page by page, and taking an expert through what would be a longer and less

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efficient deposition, in my opinion.

MR. BOATMAN: And their availability.

THE COURT: Well, on their availability, Mr. Boatman, my point is you get on their calendar in December, when the plaintiffs' expert report is produced.

Thoughts from defendant on this issue?

MR. NORTH: Your Honor, I think we can do it in less than two and a half months. It just always seems — the Court's idea makes some sense, I think, but there are always logistical problems. I would like to see us at least keep a two-month window there just because I think we'll have a lot of scheduling issues, particularly with some of these experts.

THE COURT: Okay. I understand your points.

I think -- I think this overall schedule is pretty reasonable. And in light of what you said, I probably won't confine you to three weeks on expert depositions. But I don't generally -- or I should say I don't cheerfully agree to extend litigation schedules. I want you to approach this with the assumption this is the time available so that we get the work needed done, because I'm of the mind that in litigation, work expands to fill the time available, and the best thing a judge can do is hold to a deadline to get the work done.

So I think it's a reasonable schedule. Because it's reasonable, I'm not going to be of a mind to extend it, so we'll need to really make sure we get the work done to stick

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to it.

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All right. Your proposal with respect to bellwether selection is fine. My question is are you going to be ready by March 1st to give me a detailed proposal? That is very early in the discovery process. Maybe you will be. But what I would like when we get to the bellwether selection process is to have that discussion and establish the process once, and not have three or four iterations of a discussion about it.

And my question is whether in five, six weeks, you're going to be ready to come in and say, here's how we're picking bellwethers in this case. In part, when we don't even know the number of cases and the filters that are going to be at issue in those cases, et cetera.

MR. NORTH: Your Honor, I think that we could be prepared to give the Court an idea of a process. Sort of how we should select them, the parties together with the Court's approval and input, how we identify those. My concern is if we wait too long to start identifying them, identifying potential bellwethers that are going to be worked up specifically, it takes time to get medical records, exchange fact sheets, depose plaintiffs, depose treating physicians. And if we want those cases to be ready for trial by May 19, 2017, I don't think we can wait too long to start that process. At least just get the ball rolling as to they designate some candidates, we do, the Court decides, or

whatever process we present the Court approves of.

MR. LOPEZ: I think that's true, Your Honor. I think once we get your scheduling order for the generic discovery, it's not like we have to recreate the wheel here. The process, this bellwether process, and there are other MDLs that are just now — we'll just incorporate those dates based on the dates that the Court orders with respect to generic discovery.

And I think, as Mr. North said, it's going to be a process that we're going to submit to the Court. He's probably going to suggest a certain number of cases, and with the way they get selected, we may agree on some of that. But I think we can do that in five weeks.

THE COURT: Okay. All right. I will adopt your proposal.

All right. Let's talk about the issue that begins on page 5 of your report, which is ESI and previously searched custodians.

What I want to do is talk through the various specific categories that are addressed, such as the need for discovery of system architecture, plaintiffs' desire to find out what was collected from which custodians, et cetera.

Probably ought to do that before I give you my general views, because I'm undoubtedly going to change them.

Why don't we get specific and talk first about this

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request from the plaintiffs for discovery related to system architecture. The defendants' response is that's an extraordinarily broad request; if the plaintiffs will narrow it, the defendants will produce somebody, an IT person, for an interview. Let me give you an observation and get your thoughts.

Before December 1st, Federal Rule of -- Federal Rule of Civil Procedure 26(b)(1) said that "a party could obtain discovery regarding," and I'm now reading from the older rule, "the existence, description, nature, custody, condition and location of any documents or other tangible things and the identity and location of persons who know of any discoverable matter."

So clearly discovery to figure out where information was, was permitted.

That phrase was taken out of Rule 26(b)(1) on the December 1st amendments. But the advisory committee note very clearly says it was taken out because it was viewed as unnecessary. Because it's widely recognized you can obtain discovery of where relevant information is located.

Isn't that exactly the system architecture discovery, Mr. North? I mean, don't they have the right to find out where relevant information resides within Bard so that they can tailor their discovery to get that relevant information?

MR. NORTH: Your Honor, they actually have that

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right, and we're not attempting to deny them. I think there's been some difficult, and not because of lack of trying, but communication between Mr. Stoller and ourselves. Our problem is they just want information about everything. We want to give them — the problem is we're a large corporation with divisions all over the world. Only three facilities really deal with these filters. We are not a corporation that has the same systems in the angio med division in Germany as we do in the manufacturing facility in Puerto Rico. Different systems.

We need to focus on the systems of the facilities we're suggesting that have involvement with filters, not facilities that make latex catheters and do nothing else, not those that make hernia mesh implants.

That's why we had proposed, or Mr. Stoller proposed and I think the parties are in agreement, we're going to give them an IT person, and I think schedule an informal discussion, Mr. Stoller suggested very soon, to talk about this so that he has an understanding of what we're talking about, and give him all the details that he needs about the systems for the facilities that are involved with the filter.

It's just the breadth of this question that asks for facilities that have no relevance here, have no involvement with the filter, and would be almost impossible for us to handle. But if we focus on those facilities and, you know, if

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he thinks there's a fourth facility that I'm overlooking and he finds out, we'll give it to him on that. I just don't want to be in the impossible position of trying to provide information about this 500 facilities throughout the world.

THE COURT: Mr. Stoller, what's wrong with that position?

MR. STOLLER: I would say as a general proposition, there's nothing wrong with that. The problem is, as always, the devil is in the details. And I have said to defense counsel I can approach this question from top down or bottom up. But at a 40,000-foot level, we need to have some understanding of how they're organized. And if it's information silos, and if they say to us, look, we've got 50 information silos and they're A through double Z, or whatever that ends up being when we do the alphabet, and A is this type of filter and B is this type of filter and C is this type of filter, and then D, E, F, and G are all, I don't know, transvaginal mesh, and these other ones are these other things, then I can very easily -- we can look at that picture of all those silos and say, all right, these are the ones we need to focus on. You've told us enough that we know that those giant silos are irrelevant without getting into drilling down and okay, how are those organized. Because I don't care. Reasonable -- reasonably relevant information is not likely to exist over there. I don't need to talk about those things.

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and part of the problem is we're not getting past that level, is just tell me generally how it's organized and how — what — how the information is segregated so that we can eliminate those from consideration. And then, more importantly, drilling down on whatever — again, if they're silos, they're silos. I'm assuming the system is not wholly integrated so that people in these other divisions have the ability to get into filters and vice versa. If that issue goes away and we can drill down on, okay, what's within your information systems as they relate to the filters here, how are they segregated? How is the information divided?

The problem is, Your Honor, we're two-plus months past the last time we're here, and I'm no further into getting that information or understanding about how is that information organized. I can't begin to understand whether they've actually collected the relevant information without knowing that and I'm -- it is sort of you don't go past go. They said, well, you're too big to ask the first question, so we can't even get to the second one.

THE COURT: Okay. Give me just a minute.

All right. On this system architecture issue, what I think I'm going to do in my order after today is say that two things should happen. One is either in an interview or in a 30(b)(6) deposition, preferably in an interview, Bard will

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provide general corporate-wide information on the corporate organization and information systems so that the plaintiffs can identify filter specific silos and distinguish them from other irrelevant silos. That's the 40,000-foot level, but I think they need that.

Secondly, once that is done, the plaintiffs may conduct an interview or a 30(b)(6) deposition which is limited to the architecture of systems reasonably likely to contain information related to the filters at issue in this MDL proceeding.

I'll use language something like that so that you can drill down on the architecture of the relevant systems, but there's no point doing that on the irrelevant systems. But I agree the plaintiffs have to be able to at least have some sense for what are the relevant systems.

That's the order I'm going to enter with respect to system architecture.

Let's talk about the second category, which is the plaintiffs want to identify what information has been collected from which custodians.

Let me pause for -- to make just a comment to you.

On that last issue we just covered, I think you all are good lawyers. I think you're reasonable people. You could have resolved that in a half-hour conversation.

There are tens of pages in this memorandum devoted to

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that system architecture issue, I think. I haven't read it for two days, but there's a lot of ink on that. We don't need to -- we don't need to have me resolving that kind of stuff, and we certainly don't need to be spending a lot of time on briefing. So I would just encourage you to recognize you need to be as cooperative as you can to move the MDL forward on these kinds of issues where I think both sides can get the information that you need.

My question on this issue of what has been collected from which custodians is why is this needed? And it comes from this perspective. I certainly understand the need for a party to ask that question when there's reason to think that what's been produced from a particular custodian is incomplete or is inaccurate in some way and you've got a reason to think I haven't got everything that's relevant.

But in the typical case, where a party produces documents and says, these are from Mr. Jones' files, it's not the typical practice for the other side to say, okay, I want to take a deposition of the person who reviewed Mr. Jones' files and I want to find out which documents they looked at, which documents they didn't look at, which documents they set aside.

We normally don't do discovery on that for good reason. But that seems to me to be in effect what the plaintiffs want to do. They want to find out what did you do

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when you went to each custodian? How did you search for the information? How did you make decisions about what was or was not responsive?

If there is not a reason to think that it was incomplete or inaccurate in some way, why do we spend time on that kind of discovery?

MR. STOLLER: Can I --

THE COURT: Absolutely.

MR. STOLLER: A little bit easier on the mic for me than have to go lean over.

So let me start with the following: And I think you asked a good question, but talk about -- start first with we're in a bit of a different situation than a normal case.

In a normal case I would come in, I would serve document requests, and you -- the opposing party would object, hopefully not, I've well drafted them in the first instance, but then give documents in response.

And it would say typically, among other things, you know, defendants produced all documents responsive to this request and they're identified at Bates labels ABC 1 through 257.

What we face today, particularly with the new plaintiffs and my clients who have filed complaints in this MDL phase today, is we have been given a large set of documents, and that may a bit of an understatement to call it

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large, and they're undifferentiated. There are Bates labeled prefixes that have different letters assigned to them without designation as these are this type of document or that type of document. And there are, in just three of those, one is about 2,100,000 documents -- pages, excuse me. Not documents, but pages. Another is about 250,000 pages. And another is another 250,000 pages. So what I'm looking at here is a giant pile of uncategorized, unassigned documents.

And the defendants said it in the first time we were in front of you and they said it this time, as well, that, Judge, they shouldn't get to take more of this discovery and force us to go do this again.

And so what I'm left with is saying, okay, well, have I been given — if this is what I've got to live with, as a brand-new plaintiff who hasn't had an opportunity to serve any discovery requests, if I've got to live with that, I need to have an understanding that they've given me a reasonable collection of all the of the relevant evidence, that they've gone to the places that we identified in information systems that are reasonably likely to have relevant evidence, that they've actually collected it, because, to your point before, the rules do contemplate, and I think very clearly, that we're allowed to get system architecture. But having system architecture and knowing where information is, is of no use if I don't know that they, defendants, in fact, went out and

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collected it.

And I'm not even talking about their review process. I'm not talking about eyes on documents and how did you select one document versus another, which would be, in normal circumstances, sort of core work product stuff, and not discovery.

But knowing, to use an example, that they have a silo on the recovery filter information, if they were organized this way, and it had five folders in it, and each of those five folders had five subfolders. So we've got 25 folders. And I know that for A through N, and then T through the end of the alphabet, that there's -- there's ESI going to be there. Based upon the way that they've structured system, that's going to be reasonably likely to have information relevant to this.

That information becomes utterly useless unless I know that, in fact, they went in and gathered it. If they went in and said, well, we're not going to tell you what we took from that system architecture, knowing what the system architecture is becomes utterly irrelevant.

It also leaves me unable to look at that pile at the end and say, okay, the process that you guys went through when you created what is effectively a document depository here for me and saying I've got to live with it, how do I evaluate what at the end is this a reasonable set of documents that contain

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the evidence that's discoverable or mostly likely discoverable in this case?

In working backwards, you have to start with where is it? Did you get it from those locations? And that's the question about collections: Did you actually go out and gather it? And then there's the question of what did you do to review it?

And in the old-world case, where we sat in large conference rooms and everybody had boxes and boxes of documents and you put eyes on every document, we never got into that discovery. In a world where people are using electronic terms and electronic searches and predictive coding, I think the rules are a bit different. As you mentioned before, that's more transparent in modern discovery because there aren't those individual decisions being made on a document-by-document basis, it's an electronic review that's given over to a computer.

Without information as to step 2, what did you actually gather, you can't make the connection from step 1, which is what is your architecture and where did you keep it, to what was produced.

If I go -- to use my example, if I have those -- that silo with five folders each with five subfolders, and 23 of the 25 have ESI in them that's likely to be responsive in this lawsuit, and I choose and say, well, I'm only going to collect

out of A through E and I'll just ignore F through N, which has relevant stuff, and I never -- as a plaintiff, never know that they haven't done that, how can we assess the reasonableness of what they've done?

THE COURT: Well, Mr. Stoller, let's -- one of the things you are not addressing is the fact that even though you are new to this case with new cases and haven't done it, there are other lawyers in this room who have made specific requests for all of those documents.

So my question is let's assume this was just a new case to start and you served a document production request on the party and they said here's our 2 million documents in response to your request. Your point would be, I think, you've got to be able to ask them where did you get it? Which folders did you search in every case? Otherwise you won't have the assurance that you feel you need that they have made a reasonable production.

MR. STOLLER: I don't -- I think my example is a bit different, because in my request, if this is a new case, we're not in an MDL, and I serve a set of 10 -- let's be unrealistic -- I serve 10 document requests, I think under the rules you don't just get to go, here's 2.5 million documents. I think you've got to produce them as they're kept or identify them in responses, rather than what I would characterize as classic document dump.

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This is not a individual case, and document repositories are commonly created in MDLs and large-scale litigation. But when you have a document repository like that, you've got to have an understanding that the documents that they're putting in there have been — have gone through the process to make sure that they've taken the reasonable steps. If you can say this is what everybody, every plaintiff from here on out, has to live with, they have to demonstrate that they've taken reasonable steps to ensure that that depository has the documents that are reasonably — were identified from the systems as the — at the locations where relevant ESI was likely to exist, actually gathered, so you can't just leave it behind, and then gone through a reasonable process to determine, of that giant pile, what's going to be put in.

There is no way for me to handle it unless I get to go back and say, hey, Bard, here are my document requests for my case.

THE COURT: Well, are you saying what the defendants should be required to do is say, we went to the hard drive on the laptop of Mrs. Smith, who was an assistant engineer who worked on the recovery filter for two years, and among these two and a half million documents, here are the documents we got off of her hard drive?

MR. STOLLER: No, I don't think you have to take them

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back to that. The way -- and that's not what I've asked.

What I've said is, and usually it's a logical progression,

right?, which is identify where it is, and then show me that

you took -- once you've identified it, again getting back to

my example, the 23 subfolders that are determined to be places

where it is reasonably likely that the ESI exists, show me

that you actually collected it. No more than that. If I know

that that's been collected, we don't have an issue.

THE COURT: Well, so if they then respond to you and say, okay, in folder 21 we looked these two times and we gave you 3,000 pages of documents out of that folder, are you good? Is that all you need?

MR. STOLLER: I don't think it works that way.

Because there's an intervening step, right? Which is that

before it gets to me, they go through a review process, and

that's a separate issue.

I think the answer is, again, location, make sure you get it, it then goes into the pool. And -- which is the third step, is once you have it in the pool of whatever's there, what review process are you taking to get there? That's a separate question.

THE COURT: Well, tell me exactly what you need for them to tell you about folder 21 of these folders that you say -- you characterize as reasonably likely to contain relevant information. Exactly what should they be telling you

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about what they did with folder 21?
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                       MR. STOLLER: Well, to use that folder as an over
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               simplified example, it would be we went to folder 21 and we
               collected all the ESI from folder 21.
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                       Typically, when I hire an outside --
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                       THE COURT: What else do you want to know? Is that
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              everything?
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                       MR. STOLLER: On that step? On collection?
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                       THE COURT: No. I'm talking about where we're going
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              with this.
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                       MR. STOLLER: Well, then folder 21 goes into the
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              pool. So if we went to folder 21 and 22, and then we have a
              pool of ESI.
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                       THE COURT: Okay. But you now know they say we got
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              the ESI from folder 21.
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                       MR. STOLLER: Correct.
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                       THE COURT: What else do you want to know from them?
                       MR. STOLLER: As specific to folder 21?
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                       THE COURT: Right.
                       MR. STOLLER: Nothing. Once I know that that's a
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               location of relevant ESI and that it's, in fact, been
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               collected -- well, and it's been preserved and not destroyed.
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              But once you know those things, then that's a question -- then
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              that part is done.
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                       The next step is now that all of the data from
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folders 1 through 21, whatever's been gathered and should have been gathered, what did you do with it to either reduce the pool, and here they used a key term search process, right, where they had -- you have a big pool of ESI, and then they take it through a key term search process to reduce it down.

But the question is did we carry through from we've located -- we've located a position where relevant ESI is reasonably likely to exist, did we gather that and put it in the pool? And that's all the collection information is about.

THE COURT: Okay. So you get a yes answer. You already know the search terms they have used.

MR. STOLLER: Correct.

THE COURT: Is there anything else you need to know to satisfy yourself on this general category we're dealing with of ESI production in this case?

MR. STOLLER: Yes. I need to know the algorithm they used in terms of the — the search terms algorithm, and whether they tested the results of both the responsive and nonresponsive to see if those were reasonable, that algorithm was a reasonable way to try to eliminate nonrelevant information and identify relevant information.

THE COURT: Let's say they give you the algorithm. They say, we ran these key terms using this algorithm. Now you good? What else do you need to know?

MR. STOLLER: I need to know whether they did

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testing.

THE COURT: Okay.

MR. STOLLER: And if they did testing, what those results were.

THE COURT: So you want the results of their testing?

MR. STOLLER: Yeah, because if they're testing -- if
they did testing and it showed -- the problem with key term
searches, Your Honor, is that they're both over-inclusive and
under-inclusive. If I say to go search for a filter, I'm
going to hit a bunch of stuff that has nothing to do with
this: coffee filters, air filters, things of that nature.

I'm also going to miss a number of things because it's nonspecific. People may not call it a filter. They may call it -- I don't know, they may use a different term for it. They may misspell it. There's all kinds of reasons that you would miss it.

And one of the things that ESI vendors do, in my experience, and what they should be doing, and I think what the cases say they should be doing, is just because you run -- you've tried -- if you're going to use a key term search, one, you need to create an algorithm that is best designed to try to capture the relevant information, which means first coming up with appropriate key terms in the first instance, and then second, crafting an algorithm such that you're doing your best to walk the line of capturing relevant information and

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eliminating irrelevant or nonrelevant information.

But you've got to back and test to make sure you're, in fact, doing that. You can't live in an ivory tower and say, gee, this sounds really good without looking back and saying, okay, let me take a random sampling over here of all the stuff I've discarded and said is irrelevant. Am I actually performing relatively well in the assessment I've made that this is a good search? It may not be a good search for the reasons we have identified. Maybe, as an outsider, I don't appreciate how people are typically terming things.

Predictive coding, which has not been used here, tries to get around that in a different way. But when you use search terms, key terms, you run into these significant problems of they're both over-inclusive and under-inclusive.

What vendors -- I won't say "typically," but what the vendors I work with do and what the cases support doing is going back and looking and making sure, look, when you've discarded all of this as nonrelevant, have you looked at it and said, okay, we're doing a good job? Or is it not doing a good job? Look, we did a random sampling and we're finding like 10 percent of what we randomly sampled are relevant documents, and we need to retool the algorithm in terms of what we're running through -- all the ESI through to filter it to determine what's going to be produced.

THE COURT: So my understanding is you want to know

what folders they searched or, as you say, what custodians, you want to know the algorithm they ran with was keywords you're already in possession of, you want to know what quality assurance testing they did. And that's all; right?

MR. STOLLER: I think at a relatively high level, yes, that's it. The devil's in the detail.

THE COURT: What's at the lower levels.

MR. STOLLER: So the question of what you said, I want to know the custodians, they've given me a list of the custodians. But telling me somebody is a custodian and I went and got their documents doesn't necessarily have -- is too blanket information, it doesn't tell you the details.

Let me give you an example. Let's call me a custodian of my information at my law firm at Gallagher & Kennedy. Sitting at my desk, I have a desktop, it's got a hard drive. I've got an iPad that may or may not be linked to our system. I've got a phone that may or may not be linked to our system. I've got thumb drives that may or may not be linked to our system. I could have data on all of those places, depending upon how I routinely keep my information, my work information, and what the company's policies are about that.

I also have access into the systems. On our systems, and I won't say that ours are exactly like everybody else's, but I think they're relatively standard for a law firm. I

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have access to certain shared drives. I can go on and say, all right, here's the C drive. And on the C drive, it may be that everybody in the firm can put things on the C drive and access things on the C drive, or it may be a limited pool. In my case I have access to about, I think if I pulled it up yesterday, six shared drives.

I also have access to our document management system, where everybody's got a different one, but any firm of any significant size has got a document management system. I create a letter, I write a letter to Mr. North, it's a Word version, I save it there, it's documented, it's stored on our system, accessed through our document management system. When that becomes a final letter, a .pdf of it is saved on the system. Same thing. I can create documents and save them there. Maybe Mr. Boatman writes a letter. I can access Mr. Boatman's letter. ESI can show Paul got in and played with it a little bit. Those sort of things.

We've got -- beyond that, we've got other similar type of document management software --

THE COURT: I understand the point.

MR. STOLLER: You get the point. So there's all these different points of contact and places where I'm creating, storing, accessing, modifying ESI in the system.

When you say somebody is a custodian for their records and I went out and collected the records for the

custodian, it leaves open the question of, of all those different locations, what did you actually gather? Did you just go and get my hard drive?

THE COURT: I understand the point.

MR. STOLLER: Sure.

THE COURT: What is it you want?

MR. STOLLER: I want the description from them of when they call someone a custodian, because they've given me a chart that says -- has a list of names and has a quantity of data. But I don't know from where they're collecting that data. They --

THE COURT: So do you want them to tell you that we went to Mrs. Smith's hard drive, the assistant engineer, during the recovery period for a two-year period, we looked at her hard drive, we interviewed her and asked her what thumb drives do you have, we -- I don't know if they had -- if she had an iPad back then. Probably not. But do you want them on an employee-by-employee basis to tell you everything they looked at for that employee?

MR. STOLLER: I don't think it would need to be done at that level, because I think there's going to be general propositions. Typically, again, in a large situation, when we hire — and I recognize that they did not in this case hire an outside vendor to do collections, but you get an outside vendor collection report, and it details those things.

But my suspicion is, again, you're not going to be — except there may be exceptions, and I'd obviously like to know, if that is the case, where they're noted. But generally you're going to say the proposition is, look, Paul is a custodian for the hard drives where he stores information, and we went and got his stuff there.

With respect to shared drives, we're not treating him as a custodian, but here's what we did for the shared drives.

With respect to the document management system, we're not going to treat Paul as a custodian, but here's what we did to get the information from the shared drive, and we ran searches where Paul is an author, where Paul is a. I forget how they term it on us, but Paul is a subsequent user of things of those effect, so we know.

Right now what I've been told is they collected 1471 megabytes for Shari Allen. That can't possibly give me the information to make the connection from where do you store your ESI and did it make it over there into the pile that's actually reviewed. And by "reviewed," I mean against which you've run your electronic searches.

THE COURT: Okay. I've understood what you said. Mr. North.

MR. NORTH: Your Honor, I am sensitive about waiving privilege issues, but I think that some context will be helpful to the Court, and perhaps to Mr. Stoller. I thought

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he was aware of some of this, but maybe not.

The original searching of ESI occurred in October of 2005 through January of 2006. It was performed by my office. It was performed mostly by Mr. Lerner over here and myself.

We went to four different facilities of Bard. The four facilities that had some involvement, and where custodians or people involved with the filters were identified.

We talked to 70-plus people. We walked into their offices and we sat down in front of their computers and we asked them, please, identify for us where you keep everything. We talked about their e-mail folders. We talked about shared drives they have access to. We talked about departmental drives, regulatory affairs drives. We talked about quality assurance drives, R and D drives. We talked about loose media. We talked -- you know, jump drives, things of that nature. CDs. Marketing materials.

We talked about the file cabinets. I probably saw half the file cabinets in Tempe, where we identified and they showed us every single document that had to do with filters.

Both the Simon Nitinol, the G2, and the recovery filter. We went through and identified everything. We even went to warehouses and identified where people identified things. We downloaded all the electronic information, we had all the hard copies scanned. And that formed the basis of what we did in

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2005.

Now, that seems, I suspect, a little archaic now in 2016, but this was at a time in 2005 when we had two lawsuits pending. We — the company was not prepared and did not see the necessity at that point to hire a vendor. It was simply attempting to preserve the data in the event that this litigation ever became more expansive.

But we went through all of that effort. We have provided the plaintiff with -- and over the years, that effort has been updated, both by us and by an outside vendor who got involved about 2009 and has been involved since then.

Overall, we have, I believe, approximately collected data from 181 custodians. We've provided the plaintiff with a list of each of those custodian's name, the amount of data that was collected from each of them, when it was collected, and whether it's been produced.

Now, in a perfect world, we might be able to tell Mr. Stoller that when we walked into Rob Carr, who is the principal engineer on the recovery filter, and we sat down in his office, we chose folder A, Z, and F off of his computer. We don't have that kind of drill down detail to be able to give him.

Basically what we had to tell him is that in that initial search of 70 custodians, the lawyers for Bard went person to person, door to door, facility to facility, and

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tried to ferret out every shred of paper and data regarding these filters that we could.

Now, over the years, if I can go over to another issue that Mr. Stoller says, is complaining about these search terms and asking for algorithms. A lot of what he's saying might make more sense if this was a brand-new MDL -- well, it's a brand-new MDL, but a brand-new litigation proceeding. But as the Court intimated, there's been a long history here.

These search terms were not selected by us. There were 27 search terms selected by the plaintiffs' lawyers in the first group of lawyers handling litigation in the 2010, 2011 time frame. They identified 27 search terms.

The application of those search terms to all of the material that they've collected over the years resulted in the production of over 2 million documents. In 2012 --

THE COURT: Let me interrupt you for a minute. You just said the application of those search terms to all of the material collected over the years. So are you saying --

MR. NORTH: I'm sorry. I did misspeak. I believe it was applied to custodians they identified and certain shared drives.

THE COURT: So in 2010, 2011, when these 27 terms were used, did you have this information that you had collected organized by custodian so that you could go search a particular custodian?

11:51:38 1 MR. NORTH: Yes. 2 THE COURT: Is it still organized by custodian? 3 MR. NORTH: Yes. I have to look at my expert on some 4 of these questions, but, yes, Your Honor. 5 And everything that we have produced, Your Honor, has 11:51:46 the metadata that says where it comes from. What custodian it 6 7 comes from. 8 Now, in 2012 and 2013, Mr. Lopez and his firm 9 requested additional electronic discovery, and we went and 11:52:11 10 litigated some issues regarding that in the Phillips case. 11 And the magistrate there issued a series of rules. And 12 there's some hearing transcripts. There's some affidavits prepared by our ESI vendor that were submitted there for the 13 magistrate's review. 14 The magistrate there allowed searches of 20 11:52:28 15 16 additional custodians. They allowed --17 THE COURT: This is when? This is when? MR. NORTH: This is 2012 to 2013. A several-month 18 19 period. 11:52:44 20 THE COURT: And you say 20 additional custodians? MR. NORTH: 21 Yes. And they were allowed to choose ten search terms, anchor search terms, and those additional search 22 23 terms were run against not only the new custodians they 24 identified, but also against the custodial files of those 11:53:08 25 people who had been previously searched.

11:54:49 25

So we have given the plaintiffs all the detail of that. We -- as I've said, we've given them a list of the custodians from whom data we received, the data -- amount of data from each custodian, when it was collected, and when it was produced. But we just cannot provide -- it's just not available, the drill down data, as specific as they're asking for.

And I believe, Your Honor, too, that what we have provided more than qualifies or satisfies the duty under the federal rules to provide them with as much history as we can providing the -- concerning the prior productions.

THE COURT: What about algorithms and quality assurance checking of the results from your search terms?

MR. NORTH: I'm going to let Mr. Lerner address that because he is more familiar. He is our day-to-day contact with the ESI vendor.

THE COURT: That's fine. That's fine.

MR. LERNER: Your Honor, the keywords that were used initially were just negotiated keyword terms. This happened like in 2009, 2010, the initial keywords. There's no algorithms for those keywords.

Subsequently in 2013, in the *Phillips* case, the plaintiff asked the -- asked to use those same original keyword terms, plus they had additional ones. We used those, and our vendors did some analysis of some of the keyword terms

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they were suggesting, and we did a lot of briefing on that but -- and they reviewed things for whether the new keyword terms they were suggesting would have positive or negative response rates. But there's not any kind of algorithm I'm aware of.

And also I would note that, you know, a lot of standards for ESI kind of move up and change over time. So the perfect standard that you have today is not the same as it was five, six, seven years ago.

THE COURT: Okay. So I under- -- and I know this is evolving and everybody's learning as we go along. But I understand you to be saying that it was just a straight keyword search in the initial searches done in 2009, 2010, you just got documents as to which there was a hit with any keyword, and then you looked at them.

MR. LERNER: Right.

THE COURT: And I understand you to be saying that's the same way it was done in the *Phillips* case. There was not an algorithm that was judging proximity to other words, number of words, other things.

MR. LERNER: There was not an algorithm that was used. You know, the initial terms were very broad terms. We used the word "filter," we've used the word "recovery," "Simon Nitinol," "G2." So that actually in retrospect, they were overly broad, they brought too much information in.

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And then in 2013, the plaintiffs had some additional
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               terms, and they added, you know, various connectors they
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               wanted to use, like over 100 connecting terms.
                        THE COURT: That was part of Phillips?
11:56:26
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                        MR. LERNER: That was part of the Phillips.
                        THE COURT: That was besides these ten anchor search
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         7
               terms?
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                        MR. LERNER: And I think that -- for one of the of
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               exhibits, we have a submission from our ESI vendor that goes
               through a history of --
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                        THE COURT: Right. I haven't read that yet, but I've
         12
               seen that report.
         13
                        Well, so when you did this initial keyword search in
               2009 and 2010 with words as broad as "filter," it produced
         14
               undoubtedly --
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                        MR. LERNER: Some false positives.
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                        THE COURT: -- lots of irrelevant material. What did
              you do to winnow it down to what was actually produced?
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                        MR. LERNER: We had reviewers reviewing documents,
               and the general principle was if it was potentially
11:57:02 20
              responsive, unless it is clearly, you know, not relevant, mark
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         22
               it as responsive.
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                        THE COURT: So they had people going page by page,
              eyes on the documents, saying relevant, irrelevant?
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11:57:16 25
                       MR. LERNER: Yes.
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11:57:18 1 THE COURT: And everything they said is relevant --2 well, were they doing a privilege review at the same time? 3 MR. LERNER: Yes. THE COURT: Were these lawyers? 4 5 MR. LERNER: Yes. 11:57:26 THE COURT: So they would say relevant, irrelevant. 6 7 And as to relevant, they were saying privilege or work product 8 or not privilege or work product? 9 MR. LERNER: Right. THE COURT: And did you produce everything that was 11:57:34 10 11 in the relevant side and not privileged or work product? Is 12 that in their document depository now? MR. LERNER: Yes, Your Honor, that's my belief. 13 THE COURT: Okay. So I'm understanding from what 14 Mr. North said and what you said that if Mr. Stoller noticed a 11:57:53 15 30(b)(6) deposition and he asked, when you went into the 16 17 office of Mrs. Smith in November of 2005, what file cabinets did you look in, what drives did you look at on her hard 18 drive, what other devices did you consider, you don't have 19 that information recorded? 11:58:21 20 21 MR. LERNER: Not as specific as that. I can tell you 22 generally right now here's the source of the information. 23 you go into a custodian's office, they have their e-mail, they 24 have things on their hard drive, there's a personal network 11:58:35 25 drive that they have --

11:58:37 1 THE COURT: You can say what you intended to look at, 2 but you don't have a record that when I walked out of that 3 office, I've looked at her hard drive, I've looked at the shared drive she has access to, I took the CD on her desk and 5 loaded it and searched that. Do you have that information? 11:58:50 MR. LERNER: I have some records that I -- during the 6 7 collection process that I would have kept in 2005 and overall, 8 but the level of detail that they're requesting, it's not in that level of detail. We interviewed 80, whatever it was, 70, 80, 90 people over a period of probably weeks or months. 11:59:13 10 11 THE COURT: Okay. All right. Thanks. 12 Did you have more you wanted to say? MR. LERNER: No. 13 THE COURT: Mr. North, did you want to add? 14 MR. NORTH: No. That's all, Your Honor. 11:59:22 15 THE COURT: Okay. Let me ask --16 17 Well, Mr. Lerner, one other question, and you can just pull that mic over. 18 Am I correct that you're confident today that your 19 search or your keyword searches throughout the history of this 11:59:58 20 litigation have not included any algorithms? It's just been 21 22 straight keyword searches? 23 MR. LERNER: Yes, Your Honor. The search in 2013 24 that our vendors, our respective ESI vendors had been --12:00:14 25 submitted some affidavits on, they had -- it was about the new

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key terms that were being suggested and whether -- what the
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               failure rate was, or if we add this keyword term, what is the
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               relevancy of it. If we apply the original keyword terms, what
               was the -- they did some sampling of that, and that's included
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               in that report. But I'm not aware of any kind of algorithm
               that exists that makes it --
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                        THE COURT: I think you phrased it the same way you
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               did up here, but when you say you're not aware of it, are you
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               saying it might exist and you don't know, or are you confident
               it doesn't exist?
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                        MR. LERNER: I'm pretty confident it doesn't exist,
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               but I wouldn't mind just confirming with our ESI vendor.
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                        THE COURT: Okay. Would you call them over the lunch
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               hour?
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                        MR. LERNER: Okay.
                        THE COURT: We're at noon, Mr. Stoller.
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                        MR. STOLLER: Can I make one point before we --
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                        THE COURT: You can make one point.
                        MR. STOLLER: I have the report from the ESI
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12:01:04 20
               vendor --
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                        THE COURT:
                                    I'm going to read it at the lunch hour,
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               so you don't need to point out anything to me in it.
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                        MR. STOLLER: I'm not saying this is what they used,
               but it gives examples of exactly what I'm talking about.
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12:01:13 25
               They're proposing different alternatives in the Phillips
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12:01:18
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               case --
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                       THE COURT: Is that the one that's the exhibit to
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              your joint report?
                       MR. LERNER: Yes, Your Honor.
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                       MR. STOLLER: Your Honor, on page -- there's one on
              page 5 --
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                       THE COURT: Of what?
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                       MR. STOLLER: The proposed -- they call it a search
               string.
                       THE COURT: Page of 5 of what?
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                       MR. STOLLER: I'm sorry.
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                       Richard, do you know actually which exhibit it is?
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                       MR. LERNER: It was a letter --
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                       MR. NORTH: Document 451-3 --
                       MR. STOLLER: Yeah, that's it.
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                       MR. LERNER: -- on the docket.
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                       THE COURT: Yeah, I've got it in front of me. It's
               21 pages long. And it's a letter from -- it starts as a
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               letter from your firm to Mr. Stoller. So is it the report
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12:01:54 20
               that's attached to that letter?
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                       MR. STOLLER: There's a report attached to that
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               letter, Your Honor, and page 5 of that report has an example
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              of a search string. So you can see the complexity involved.
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                       THE COURT: Well --
12:02:13 25
                       MR. STOLLER: And I --
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                        THE COURT: Are you saying that is an algorithm?
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                        MR. STOLLER: That is an algorithm, Your Honor.
                        THE COURT: All right. Would you just try to clarify
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               that, Mr. Lerner, during the lunch hour?
12:02:23
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                        MR. LERNER: Yes, Your Honor.
                        THE COURT: Okay. We will resume at 1 o'clock.
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               Thanks.
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                    (Recess taken from 12:02 recess to 1:00.)
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                        THE COURT: Please be seated.
13:00:55 10
                        Counsel, at the rate we're going, we'll be here till
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              midnight, so we're going to pick up the pace a little bit.
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                        Before we do, Mr. Lerner, what were you able to find
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               out?
                        MR. LERNER: So the source I used in 2013 was not an
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               algorithm. They explained to me that's more used for computer
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               assisted review, and that technology was really just started
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              being used more frequently over the last couple years.
               when -- in 2010, we didn't do it, and in 2012, 2013, we didn't
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               do -- there is no algorithms that they did.
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                        They reviewed the search terms and -- because they
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               were getting so many hits and they were trying to figure out
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              how to -- how to make the keywords less, figure out what
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              keywords were good and how to narrow the scope of things, that
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               they were bringing back too many false positives.
13:01:52 25
                        THE COURT: Well, on that point, the report that is
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attached to your letter describes various efforts that could 13:01:54 1 2 be undertaken to reduce the number of hits. 3 I'm assuming this is a report that was used in the 4 Phillips case --13:02:08 5 MR. LERNER: It was. THE COURT: -- that the magistrate judge took into 6 7 account when he said do 20 additional custodians, 10 anchor 8 terms, 171 connectors? 9 MR. LERNER: Exactly, yes. 13:02:20 10 THE COURT: If you look at page 5 that Mr. Stoller 11 had pointed out, and it's a search string, about halfway down 12 the page, looks like a Westlaw or a Lexis search instruction, what would you call that, if not an algorithm? 13 MR. LERNER: You mean within the proposal number 4? 14 13:02:42 15 Where are you --16 THE COURT: I'm looking at the bottom of proposal 17 number 3, the italicized language in parentheses, last three lines in the reasoning section on proposal 3. 18 MR. LERNER: I think it's akin to like Westlaw and 19 13:03:01 20 Lexis. I'm not sure if you call it an algorithm. I think --I -- algorithms are more done with computer research and 21 22 there's mathematical formulas --23 THE COURT: I'm just having a terminology problem 24 here. 13:03:12 25 MR. LERNER: Yeah.

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                        THE COURT: But is it accurate to say that you used
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               search instructions such as what is in those three lines?
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                        MR. LERNER: Yes. And those -- I think those terms
               are taken from appendix B.
13:03:34
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                        THE COURT: Yeah, all the terms are there, but the
              way they were linked together, in other words, as I read this
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               search instruction, and I'm no computer guy, but, for example,
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               in the first set of parentheses, if the word "embolism" was in
               a document, and in the second section the word "meridian" was
               in a document, then the document would be a hit.
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         11
                        MR. LERNER: Right.
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                        THE COURT: If "embolism" was in there and nothing in
               the second parentheses was in it, it wouldn't be a hit. So it
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               is a way to combine search terms.
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13:04:08 15
                        MR. LERNER: Right.
                        THE COURT: I'm assuming you used different
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               variations of those kinds of instructions when you did your
               searches --
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         19
                        MR. LERNER: Right.
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                        THE COURT: -- right?
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                        MR. LERNER: Yes.
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                        THE COURT: And that's what you want, right,
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              Mr. Stoller?
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                        MR. STOLLER: Yes, Your Honor.
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                        THE COURT: So whether we call it an algorithm or
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not, is there a problem on the part of the defendants with
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              telling the defendants how you constructed your search
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               instructions using the keywords?
                        MR. LERNER: No, Your Honor. I thought we had
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               already provided that information.
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                        THE COURT: Well, just providing the list doesn't
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              tell them what combinations on the list you were searching
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               from.
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                        MR. LERNER: Initially for appendix A, that list
              was -- we didn't use strings, like those were the keyword
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        11
               terms by themselves.
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                        THE COURT: Right. I understand that.
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                        MR. LERNER: Okay.
                        THE COURT: But when you did the later searches, you
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              did various combinations in your searches.
                        MR. LERNER: Sure.
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                        THE COURT: I assume you've got a record of those?
                       MR. LERNER: Yes.
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                        THE COURT: Do you have any problem sharing those
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              with the plaintiffs?
                        MR. LERNER: No, Your Honor.
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                        THE COURT: All right. Well -- okay, let me ask
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              Mr. Stoller a few questions to see if we can get this
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              resolved.
13:05:17 25
                       Mr. Stoller, it seems to me what we know is we have
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the lists of who -- what custodians' documents were obtained 13:05:22 1 2 in 2005 and 2006. That's in the letter to you. We know what 3 additional custodians that were added. We know the search terms that were used. You're going to be given the search combination instructions that were used. I'll talk to them in 13:05:44 5 a minute about any testing on accuracy. We know that when 6 7 counsel went around Bard in 2005 and 2006, it was personal 8 interviews, so there's at least not a computer record of, you know, what files were looked at. 13:06:09 10 If there -- if you get the combinations -- I'm 11 calling them combinations, you call them an algorithm. You 12 know the custodians, we can find out if there's any sort of 13 testing that was done and, if so, what it produced. sounds to me like about 90 percent of what you were asking 14 13:06:29 15 for. 16 MR. STOLLER: Sounds like it would be a good way 17 towards what I'm asking for. Things remain of what don't I know, and I'll go back to the -- I think they should at least 18 be able to tell me generically for the custodians that we took 19 these types of information from these types of sources. 13:06:43 20 Again, if there's special notations --21 22 THE COURT: I understand. 23 MR. STOLLER: -- get that. 24 For the common things, like they have and we 13:06:53 25 referenced in our papers, they've got a document management

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system that used to be called QUMAS, I may be not pronouncing that correctly, but the acronym was Q-U-M-A-S, and they now use something called MasterControl. We don't know how they went through that to ascertain what documents they were going to obtain. And frankly, I guess, part of the problem is we don't know really what's in there and whether or not what would be a reasonable way to locate potentially relevant information from them, from that particular system.

So getting from the gaps of -- it sounds like based on your order, they're going to get us the information so we can drill down and understand where it is, and just to try to fill in the gap of, okay, knowing where it is, did you take reasonable steps to get it?

A fair amount of that, based on what you said, we would get, but it still seems there's other pieces of information we would need such as what did you do for the document management systems to get it. And to use my example of me as a custodian, what types of information — and I talked about this before. I said I'm willing to address it top down or bottom up. One of the questions I typically ask of a user is, okay, you're sitting at your PC, what do you touch? What do you have access to? Where do you store your documents? And I would get an answer similar to the one I gave you, which is here's the things — here's the places I have, here's the things I get and use and touch. And then we

13:08:09 1 can access and determine, okay, is there ESI there we need 2 gather? 3 I don't have that base level description, the bottom 4 up of what is a user, what is someone who deals with an IVC --13:08:18 who's in the IVC filter part of Bard's system, their information systems? Where do they -- where can they reach, 6 7 access, and touch information? 8 If I have that understanding, then it's easier -- and 9 then they can say, look, a user in this system has access to these, let's call them seven things, and we collected personal 13:08:35 10 11 stuff from A through E, and then I only have questions, okay, 12 what did you guys do to find F and G? Does that make sense? 13 THE COURT: Partially. But I don't think I want to 14 hear more right now because I'm going to propose something and 13:08:52 15 16 get a reaction from you. 17 MR. STOLLER: Do you need anything more from me, or would you like me to sit down? 18 19 THE COURT: Go ahead. 13:09:05 20 MR. STOLLER: Thank you. 21 THE COURT: Mr. North, Mr. Lerner, can you give me a 22 brief description of what you did in the way of any testing to 23 verify the accuracy of the search terms that you were using 24 and the combinations you were using? 13:09:58 25 MR. LERNER: I think the testing that was done is

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kind of outlined in that report from the ESI provider.

THE COURT: I read the report. I didn't see anything about testing. What are you referring to?

MR. LERNER: Well, they looked at -- they ran keyword terms. We had a disagreement how many keyword terms we were going to use and how expansive -- how much data that would bring back. So they tested the keywords by doing some sampling and seeing if it was high hits, and then doing some sampling about, you know, the relevance of the keyword terms and whether -- how many false positives, and they made suggestions about how to make the amount of information that came back a smaller amount.

THE COURT: Well, yeah, there's suggestions on how to reduce the amount being returned. And there's suggestions as to why -- implicitly why this would be more accurate.

MR. LERNER: Right.

THE COURT: But the kind of testing I understand plaintiffs to be asking about is once you've narrowed it down and you get your 10,000 documents, the testing would be to go in and take a subset of what was searched, a subset of what was found, compare them, and see if you're missing stuff that should have been found, if you're over-finding stuff that is irrelevant, so that you come up with some indication of how accurate your keyword search is in finding the stuff that really matters.

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Did you do anything like that that you're aware of?

MR. LERNER: I'm not aware of that, no.

THE COURT: Okay.

Mr. Stoller, did I accurately describe the kind of testing you're talk about?

MR. STOLLER: You did, Your Honor.

THE COURT: Okay.

All right. This is what I'm inclined to do. I'll give you a chance to tell me if you see a problem with it.

I'm inclined to require the parties to take four steps on these issues we've been talking about.

The first step would be -- I shouldn't say four steps. Two steps, but the first one has three parts. In the first step, the plaintiffs -- I'm sorry, the defendants would produce to the plaintiffs in the form of an interrogatory answer three categories of information. One is a description of what Bard's counsel did in 2005 and 2006 to identify information from each custodian you interviewed. What kinds of information did you look at and inquire about.

And if you've got actual records of it, my idea is to get them as much detail as you can about how you went about searching for documents in 2005 and 2006 when you walked into Mrs. Smith's office. So this would be a description of the effort that was made.

And you've said that there have been subsequent

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updated searches, a description of that, as well. The idea is to give them as clear a picture as possible of where you went to find documents and how you went about finding them.

Category 2 would be to provide in the form of an interrogatory answer, or if you think there's a more efficient way to do it, you can see if you can agree upon, the search strings you used with the keywords. The sort of thing we were just looking at on page 5 of the expert report. What kind of instructions were you giving to the computer to find documents based on the keywords. That's what the plaintiffs have been calling algorithms. We'll drop that word out, but just the search instructions.

The third point would be to confirm if it's true, in an interrogatory answer, that there hasn't been the sort of testing that I just described to see if the results from the searches were over-inclusive or under-inclusive.

Step number 2 would be once this information is provided, to have the parties sit down and talk about what more the plaintiffs think they're entitled to along these lines, and what the defendants' reaction is.

And if you are unable to reach agreement, then I will require you to provide me with a matrix which has a line for each of the categories of information the plaintiffs think they need in detail. Not, "We want general categories of information," but, you know, what specifically would you put

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into a request. So on line 1 would be the plaintiffs' request, and on line 2 would be -- I'm sorry, on the second half of line 1, or the second box in the matrix would be the defendants' explanation of why that is not needed or why it's unduly burdensome. Why you're objecting to it.

The idea would be if there's five additional kinds of discovery the plaintiffs think they need, I can look at this matrix and see exactly what the plaintiffs are saying they're needing and exactly what the defendants are disagreeing with, and I can go down and make a ruling. And I know you're talking about exactly the same issues by the structure of this matrix.

And it would need to be more detailed than the kind of things that I got in the joint report, because sometimes when I read this report, it was talking about general categories of information, and I couldn't figure out what was needed.

And I would then take that matrix, if I look at it, if I think I need to get you on the phone, I'd get you on the phone to talk through it and make sure I understand it, and I'll enter a ruling, then, on what additional information besides this first step information is needed.

Plaintiffs, any thoughts on this?

MR. STOLLER: No, Your Honor. Sounds perfect.

MR. NORTH: That's fine, Your Honor.

THE COURT: Okay. That's what I will put in the report. Let me just make another note here.

And what I'm going to do is, I'll actually come up with the dates when I do it, but I'm going to give you about probably four weeks for the first step of getting the information, and then maybe another four weeks to meet and confer and compile the matrix. I may shorten it a little bit, but the idea would be within six or eight weeks I've got that matrix back in hand so that we can move ahead on this ESI discovery issue.

All right. A second part of this that's addressed is the whole notion of preservation. Plaintiffs assert that there is a gap between the point in time when Bard says it was anticipating litigation, which would have been sometime in mid or maybe even the first half of 2004, and December of 2004, when the litigation hold was entered.

That seems to be to me the primary preservation issue raised by the plaintiffs.

Am I right about that?

MR. STOLLER: The short answer to that, Your Honor, is based on what we know, yes, right now. The other information we talked about would inform other questions --

THE COURT: I understand. I'm not saying you're waiving other preservation issues. But that's the focus right now.

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Mr. North, do you agree that there was a difference between when Bard anticipated litigation and when it issued the litigation hold in 2004?

MR. NORTH: Yes, Your Honor. Yes. There was no litigation pending at the time we issued the litigation hold, but there was some anticipation of litigation.

THE COURT: I understand.

MR. NORTH: Tied into the Lehmann report, once they saw that, that they went on and issued the legal hold.

THE COURT: All right. Well, let me tell you my thought on this. You know, we could launch down the road of doing discovery about what was or was not lost during that period, if anything. We could spend time and effort on it. We don't know if anything was lost. We don't know how consequential it was. It's a side road that doesn't get us any closer to the merits. We don't know if there are other preservation issues that might come out of this other exchange we're going to have.

We've got a new Rule 37(e) that talks about what you do when information is lost that should have been preserved in anticipation of litigation. And one of the things you have to do before you even get into the remedy phase of 37(e) is see if the information is available in other locations through other discovery. That's a question nobody's answered.

It seems to me it would be premature to launch into

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preser- -- failure to preserve discovery at this point. We don't know what all the issues are. We don't know what's been lost. We'll know more as we get through the rest of this process about what Bard's done to search for information, what's been produced.

I'm of a mind to say at this point we're not going down that road yet. If, in a few months, plaintiffs are of the view that you can concretely say it looks like some information was lost during this point and there's a good reason to pursue it, then we can address it at that point.

But I sure don't see a reason to start now into discovery of what happened between April of 2004 and December of 2004 when we've got more important issues to address.

But I want plaintiffs' response on that.

MR. STOLLER: Your Honor, my only concern on that is the one of timing and how it does interplay with other issues.

THE COURT: Pull that other mic up, would you, so we can hear you more clearly.

MR. STOLLER: I'll move them both a little closer.

The concern I have is I don't have a problem with saying, look, we don't launch headlong into preservation discovery at this point. My concern is how does that issue affect other things in the case. And this is — since we're in a, what I'll call a hybrid situation, where we've got a fair amount of past discovery, and obviously some that's going

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to be taken going forward, what I don't want it to do is bog down the existing discovery or slow up existing discovery.

And I mean that in the following way. But typically the way you discover these sort of things is you start to ask questions of witnesses, and they say, "I don't know," and then you ask them the question of, okay, well, where would the information be and what did you do?

If those types of questions are still permissible, then I think it doesn't create a problem for us. Rather than having the defense say, well, you're not allowed to ask those questions because that's preservation and destruction type of questions that the judge isn't letting go forward now. So that's the one concern.

And the other one is that because of some of this discovery's already been taken in the past, prior depositions and such, if — and I don't know what you're going to do on that front when we come to scope of discovery and what you're going to allow going forward, but if, for example, you were to say, well, plaintiffs, these deposition have been taken and you're just going to have to live with them, and nobody had the opportunity to at that time when the depositions were taken to ask the type of questions I'm talking about that would lead you to information such that we would be coming back to you and saying, Judge, you know, during this time period, this — when this — you know, back when we think they

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should have been holding on information, and we've got inferences here based on our questioning that it's not there, if we're not allowed — if we don't have an opportunity to depose some of those witness who've previously been deposed, we're not really going to discover those sorts of things.

And I realize I'm giving a sort of we don't know what we don't know kind of answer here, but unlike a normal case where I would be coming in to you and saying we're going to go from start to finish and take our discovery and we'll learn things along the way, it's not clear to me that we'll have full opportunity to do that in the normal course as we would.

Does that make sense?

THE COURT: Yeah. I understand your point.

MR. STOLLER: Okay. Thank you.

THE COURT: So what I'm going to do on this issue is the following: We're not at this stage going to launch into preservation/spoliation type discovery in terms of, you know, you setting up a 30(b)(6) deposition of their IT guy to find out what happened to information between April of 2004 and December of 2004.

If the plaintiffs believe as we get into the case that there is a good faith basis for needing to inquire into issues that may lead to Rule 37(e) remedies, you can raise them.

This ruling, however, does not prevent the plaintiffs

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or the defendants in a specific deposition from asking that witness about what information that witness knows exists related to his or her testimony, where it is stored, when it was stored. You can ask those kinds of questions. I'm not saying any questions about preservation of information or location of information is off bounds. But I want to avoid starting an ancillary set of discovery that's just focusing on spoliation issues.

So that's where we'll leave the issue of preservation for now, and the plaintiffs can raise it at an appropriate time if you believe there's a good faith basis for doing something specific on that issue.

All right. The next subject is new custodians. And my understanding is this would be searches of additional custodians not included in the original set or the 20 that were added by Judge Cobb. Plaintiffs — defendants have proposed ten to 12. But I couldn't come up with any — I couldn't see any explanation in the papers as to how you came up with that number. Where did ten to 12 come from? Why is that the right number?

Mr. North?

MR. NORTH: Your Honor, we were thinking that all the major custodians for the first two generations of filters, recovery filter and G2, have been searched. The majority of cases involved those two first-generation filters that --

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there are three later generations, the Eclipse, the Meridian, and Denali, and that would allow about four people per generation.

You know, we're not wed to ten or 12, but trying to come up with some reasonable scale, we were thinking three or four people per generation, that would allow people from quality, regulatory, research and development, and marketing. So the major four functions.

THE COURT: Well, so that approach would say that as to one generation of filters like Eclipse, we'll search the files of one person in marketing and one person in another division. Is that basically right?

MR. NORTH: We wouldn't -- we aren't arguing to confine them specifically like that. We're just trying to come up with some rough measurement. If you had 12 people and you have three additional filters that there has not been ESI extensively done -- now, the words "Eclipse," "Denali," and "Meridian" have been searched in the past from the old custodians, but if you wanted to focus on, like, the engineer that started in 2009 and developed the Eclipse and worked on the Meridian, but really was not searched earlier, you probably couldn't identify much more than ten or 12 people that hadn't been searched in the past that were specific to these newer generations.

THE COURT: Well, that's the key issue; right?

13:27:58 1 MR. NORTH: Right. 2 THE COURT: How many people are there that haven't 3 been searched in the past that are specific to these three new 4 filters? 13:28:06 5 MR. NORTH: Your Honor, in all candor, I couldn't tell you exactly. There are a lot of carryover people, 6 7 engineers. But there are some newer people. There's a newer 8 marketing manager now in the last couple of years. There's certainly a regulatory person. 13:28:23 10 THE COURT: I understand that point. Why doesn't it 11 make sense to first have the plaintiffs serve an interrogatory 12 saying, please identify employees of Bard who worked on these 13 three filters and who were not searched as previous custodians, and have you go to the company and figure out who 14 they are, how many they are, give that to the plaintiffs, and 13:28:40 15 16 then have a discussion about what --17 MR. NORTH: I think that's perfect, Your Honor. That makes perfect sense. 18 THE COURT: Is there a problem with that from the 19 13:28:50 20 plaintiff side? 21 MR. BOATMAN: Yeah, from a theoretical methodological 22 perspective, not at all. The only concern I have is if we're 23 talking about in terms of quote, unquote, custodians, is there's all these other things out there that -- again, I 24 13:29:04 25 don't know how they're defining what they're collecting from a

There's the shared drives and there's their 13:29:07 1 2 document management systems. But, to me, sitting down and working through who works on this, who's got access to it, 3 4 where's the information, and working from there to figure out 13:29:19 5 where they're going to collect is the most logical way to do it, and that's frankly what we've been proposing all along. 6 7 THE COURT: Is it Eclipse, Meridian, and Denali? Are 8 those the three? 9 MR. NORTH: I'm sorry, Your Honor? THE COURT: Eclipse, Meridian, and Denali, are those 13:29:51 10 11 the three? 12 MR. NORTH: The three, yes, Your Honor. Incidentally, going back to my two-step 13 THE COURT: process on the ESI, in the first step, when Bard is telling 14 the plaintiffs how you went about searching information for a 13:30:20 15 particular custodian, I want you to include in that the 16 17 description of how you went about retrieving documents from 18 these document management systems. I can't remember the name of them. One starts with a Q and one is Control something. 19 So include that. 13:30:44 20 So Mr. Stoller, you'll get in that initial 21 22 information a description of that, which is one of the 23 concerns you just addressed. 24 But on the new custodian -- so step number 1 will be

either by an interrogatory or just by talking, Bard will tell

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the plaintiffs what custodians worked on these three filters that have not been searched for in any keyword searches up until now.

Number 2, the parties will then discuss whether you can reach agreement on what the additional custodians will be. And if you're unable to reach an agreement, you're going to include this in the same matrix you're going to give me on the other issues. So it will be the same timing I'll set out.

All right. Let's talk about the FDA letter.

My problem in reaching a decision on this matter is I have no sense right now for how relevant this FDA inspection warning letter is in the case. I have the plaintiffs saying it is, quote, at the core, close quote, of your claims, and the defendants saying it, quote, has little, if any, relevance to the issues in this case, close quote. And I don't know who's right. I'm guessing it's somewhere in between those.

Plaintiffs want several more depositions and additional documents. The defendants say it's not relevant, and because it's not relevant, it would be too burdensome.

How do we solve that problem? I know you can say let's have a hearing, let's do additional briefing. Maybe that's the answer. But it seems to me I've got to get as clear an understanding as I can about what the letter said and why you think it's relevant and why you think it's not before I can decide, yeah, we ought to do substantial additional

discovery on it or, no, it's really not an issue in the case. 13:33:05 1 2 Mr. Lopez? 3 MR. LOPEZ: I agree with what you just said, Your Honor. I'm prepared to do that now. I mean, I can give 4 5 you -- I've got the warning letter with me. I've got some of 13:33:14 the documents that were produced. I've got things that 6 were -- that we learned for the first time. 7 8 THE COURT: How long would it take you to do that? 9 MR. LOPEZ: Probably 20 minutes or so. Maybe half hour. 13:33:30 10 THE COURT: My problem is it's 1:30. If I take 20 11 12 minutes a side and we've still got 11 issues to address, we're 13 going to run into problems. 14 MR. LOPEZ: We can have another hearing or I can give you -- if you want me to shorten it, Your Honor, just to kind 13:33:41 15 16 of give you a sense that this is not just, you know, leaving 17 out a bit of income from your tax return, but maybe more on the side of a tax evasion issue, I'm prepared to do that. I 18 mean, I've got the warning letter, I've got some of the 19 documents that we used in the deposition. I can explain to 13:33:59 20 the Court why what we discovered from these depositions and 21 22 what was produced does transcend to the very beginning of this 23 case and all the way back to the Simon Nitinol filter, 24 frankly, and to the present. It deals with all the clinical 13:34:20 25 data --

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THE COURT: Okay. You're getting into the argument. Lets hold on a minute on that.

Were you going to say something, Mr. North?

MR. NORTH: I was going to suggest as a possible alternative, Your Honor, we'll do whatever the Court wants, of course, but perhaps both parties within seven days can do a ten-page brief and just explanation and detail identifying the issues, the principal issues, and why they do believe it is relevant to the litigation, or why they believe it is marginally relevant.

MR. LOPEZ: You know -- I'm sorry, Judge.

THE COURT: Go ahead.

MR. LOPEZ: One of the issues, and maybe Mr. Stoller can address this, as I heard this ESI play itself out, I wonder how much of that is going to apply to some of the additional information and evidence we're looking for here.

But one thing I think you know from our papers, as soon as we got the first session transcript, we did serve some interrogatories -- were they interrogatories or request for production? Request for production. Whether that's a place to start or not, I don't know. But I think -- I'm prepared to do what the Court -- it's a much more important issue that goes back to the beginning of this case than I think is being represented by the other side.

Again, you know, that's -- you want to see both

13:35:37 1 sides, and I think we want a fair opportunity to show that to 2 you. 3 THE COURT: Okay. 4 Well, let's do this. For now, because I want to make sure we get through the rest of the issues, let's assume we're 13:35:52 5 6 going to do a ten-page memoranda. But if we get done more 7 quickly, I may come back to this and have you make some 8 presentations today that will at least give me a better sense of what's at issue. But for now, what I will say is let's -- you 13:36:06 10 11 suggested seven days. Is that doable for the plaintiffs? 12 MR. LOPEZ: We can do that, sure, Your Honor. 13 THE COURT: All right. MR. LOPEZ: Seven calendar days, so a week from 14 today? 13:36:20 15 16 THE COURT: Yeah. So for now, my thought is that --17 MR. LOPEZ: He tells me I'm on my own. MR. STOLLER: Ten days may be better from our side, 18 19 Your Honor, just because I know the calendars of all the folks 13:36:34 20 in our office. 21 THE COURT: Okay. Let's say that as of now it is 22 going to be ten-page memos by February 10th addressing this 23 issue, filed simultaneously, relevant exhibits attached. And 24 if we've got time today, we'll come back and learn more about 13:36:57 25 it that might modify that, but that's what we'll do with this

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issue for now.

The next issue is titled ESI and documents withheld for Eclipse, Meridian, and Denali. It's really the same issue we have been talking about; right?

MR. STOLLER: I think your prior statements would encompass this entirely, Your Honor.

THE COURT: Okay. That's my view, as well. Okay. So what I've already decided as to how we're going to solve that will apply to that category.

The next category is discovery related to the Simon Nitinol filter. The plaintiffs are saying it's the predicate device, it's relevant to efficacy, design, manufacturing of all devices; the failure rates, adverse events and complaints are relevant. Question whether later events were substantially equivalent to this filter is relevant for FDA approval purposes.

As I read that, the question that occurred to me,
Mr. Lopez or Mr. Boatman or Mr. Stoller, was if this is so
central, how is it the cases were ready to go to trial without
this discovery having been done?

MR. LOPEZ: Well, "ready" is a relative term, but —
THE COURT: Well, but my point is you got one case
going to trial in Nevada, you had cases in Maricopa County
Superior Court ready to go to trial. There's others that are
close — in other words, you have a lot of cases where

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discovery is closed. Why wasn't this inquired into if it's so central to the case?

MR. LOPEZ: Well, it was. In other words, it was not like the first time we've asked for this. We've asked, I don't know, a number of cases, including probably the first state court case we have, and our motion to have that evidence produced was denied.

And really, it probably was after all that that the relevance of the Simon Nitinol filter became important, and really, sometimes after you hire experts, all of a sudden the direction you take your case is much different than you thought you were going. And all of a sudden this predicate device becomes maybe one of the more important issues because of the 510(k) process and its performance or -- and the fact that all of the devices after it, every single one, from the recovery filter to the Denali, was required to produce in as safe and effective a manner as the Simon Nitinol filter.

We've got some data about that. It's just that we don't have a full production regarding the Simon Nitinol filter. Some of that just spilled over into the production we've got on the recovery filter and some of the other things. We've not had a full production.

So, yes, were we prepared to deal with some of this as we went to trial? We were. But I think there's more about that production, because if you look at the representations

about the Simon Nitinol filter in the productions that we've 13:40:04 1 2 gotten that don't really involved the Simon Nitinol filter as 3 a body of production, it's -- some of it is conflicting. And I think the only way to deal with that is to actually see the 13:40:20 5 data that exists for that particular filter. THE COURT: Well, let me ask you this question, 6 7 Mr. Lopez. I'm reading now at the bottom of page 39 on the 8 joint report. This is from the defendants' position. 9 What defendants say is, and starting on line 25, when Bard has inquired regarding what specific SNF materials the 13:40:37 10 11 plaintiffs desire, the plaintiffs have simply stated they 12 want, quote, everything, close quote. MR. LOPEZ: Well, I don't know whose -- do you want 1.3 me to address that? 14 13:40:55 15 THE COURT: I mean, is that right? Or are you more specific in what exactly --16 17 MR. LOPEZ: Well, I think maybe the word "relevant" was left out of there. 18 THE COURT: Even if it's everything relevant, have 19 13:41:05 20 you been specific in telling them what it is you think you should be entitled to obtain? 21 MR. LOPEZ: We have. I don't have those discovery 22 23 requests here, but we have specifically requested various 24 precise information regarding the Simon Nitinol filter. 13:41:23 25 THE COURT: In other cases?

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MR. LOPEZ: In other cases. I mean, it's fairly simple. We primarily want information regarding, you know, the performance of that device, both from an efficacy and a safety standpoint; some of the marketing and sales as they relate to that device; some of the testing that happened with that device.

Your Honor, in order for a subsequent device, a 510(k) device to get on the market, it has to compare itself in a laboratory to a predicate device. We've not seen any of the laboratory testing, the bench testing, the animal testing that's been done on the Simon Nitinol filter going back to when it first — I don't know, it was early 1990s, I think it first entered the market.

So we -- if what you're asking me, Your Honor, could we set forth with specificity those things that we want regarding the Simon Nitinol filter that is not everything, sure, and I think we've done that previously.

THE COURT: You agree, I assume, that there is no case in this MDL that concerns the Simon Nitinol filter?

MR. LOPEZ: Not yet. I know that. I know that some people are asking me. I've gotten calls from people who have a Simon Nitinol filter case, just to inquire about the case, and I know people are looking at that case. I can tell you our firm does not have any, but the potential is it could become part of this MDL.

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                        THE COURT: But as of today, it's not in the case?
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                       MR. LOPEZ: It's not.
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                        THE COURT: Give me an illustration of something you
               could learn about the Simon Nitinol filter that would
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               strengthen your claim in this case that the removable filters
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               were defective or the subject of fraud or something like that.
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                        MR. LOPEZ: All the testing results that existed --
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                        THE COURT: Give me something specific. I'm not
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               understand- -- yeah. I mean what fact could you find about
               Simon Nitinol that suddenly makes your case about the Eclipse
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               filter stronger?
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                        MR. LOPEZ: Okay. I can give you a couple examples.
                        THE COURT: I only need one.
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                       MR. LOPEZ: Just one.
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                        THE COURT: I'm just trying to understand what it is
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               you think is going to be helpful.
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                        MR. LOPEZ: Fracture resistence testing that was done
               on the Simon Nitinol filter in early 1990s, when it became --
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               when it was 510(k) cleared to show that the fracture
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               resistence of the Simon Nitinol filter was at X, and then I
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               could take that and look at the -- because it's supposed to be
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               substantially equivalent, the recovery, in every device after
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              that.
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                        Now I look at the fracture resistence testing that
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              was done in recovery filter, and it is one-third X. That is
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not substantially equivalent. We don't have that early
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              testing that was done.
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                        THE COURT: Okay. So that would help you argue it is
              not substantially equivalent.
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                        MR. LOPEZ: Right.
                        THE COURT: What are you arguing to the jury from
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               that fact?
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                        MR. LOPEZ: To the jury?
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                        THE COURT: Yeah.
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                        MR. LOPEZ: Well, that they did not -- well, okay.
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               It depends on whether or not the 510(k) evidence even comes
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               into evidence. Because there was a Fourth Circuit ruling
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              recently against -- in fact, it involves Bard and the TVM
               litigation where the Court of Appeals, after the trial judge
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               ruled that all this stuff about whether or not something got
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               cleared through a 510(k) or not is not relevant. It is how it
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              performs after it gets on the market and what does the company
               do with that.
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                        I agree with that ruling, but not every court rules
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              that way.
                        THE COURT: Well, wait a minute. You said the trial
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               court said that the 510(k) is not relevant?
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                        MR. LOPEZ: All that information --
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                        THE COURT: And you agree with that, you said?
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                       MR. LOPEZ: I agree with the Court of -- I think we
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all agree with the Court of Appeals ruling that this case should not be focused on the process of the 510(k) clearance. The focus needs to be after that clearance, the company's conduct with respect to warning, notice --

THE COURT: Okay. In light of that, I'm having even more trouble understanding how you're going to argue to the jury that the Eclipse filter is one third of X on the fracture measurement.

MR. LOPEZ: Because they want to talk about the 510(k) process and the fact that they followed -- they submitted to FDA everything that would have -- that established that this subsequent device, the 510(k) cleared device, was substantially equivalent to the Simon Nitinol filter, and what they do is they submit testing results to the FDA.

THE COURT: So are you saying that in front of the jury, if I allow it in or a judge allows it in, the defendants will say the Eclipse is good because it was FDA approved, you know, most rigorous regulatory agency in the world said it's okay, and you want to be able to stand up in front of the jury and say, well, but what wasn't disclosed was that the Eclipse filter could only withstand a third of the fracture pressure of Simon Nitinol?

MR. LOPEZ: Well, some of that is what I would say. But first of all, it's not approved, it's cleared, and the

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reason it's cleared is because all you have to do to get a device cleared is to show testing results. Laboratory testing, bench testing, animal testing results. The FDA -- compared to the same type of testing that's done on a predicate device. So if those are substantially equivalent, you get cleared. So they obviously submitted that to FDA in 2001, '2, and '3 to get their clearance.

I don't know whether there was testing done on the Simon Nitinol filter in the 1990s that shows that their ability to resist migration, their ability to resist fracture, their ability to resist perforating and tilting, is something other than the substantial equivalence testing that the FDA got.

What we do know is in the clinical world, the substantial equivalence between these two devices is the Simon Nitinol filter is here, and the risk of the -- of the recovery filter is -- many, many -- it's in the Lehmann report, the comparisons between the Simon Nitinol filter and the recovery filter. I mean, it's off the chart.

So were there test results that would have predicted that that predated 2001, '2, '3, when Bard was submitting those to FDA?

And we also have -- this actually crosses over potentially into the Kay Fuller issue, which Mr. Boatman's going to address, where certain testing was not done on the

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recovery filter that was being urged by their regulatory affairs person to do, to determine why this thing fractured in a clinical trial. They may have done that test in 1994, 1995, on the Simon Nitinol filter. We don't know.

THE COURT: Okay.

Mr. North?

MR. NORTH: Your Honor, this actually, to be in all candor, is one of my more frustrating issues to grapple with right here. And that is because we have already, in the course of this litigation, produced a large number of documents about the Simon Nitinol filter. We have produced the design history file, which should contain either the test results -- I can't say particularly right now without looking back, either the test results or summaries of the tests that were performed. We have produced the fact books, which is supposed to be, you know, more information about the development of the product. We have produced FDA submissions. We have produced a number of materials provided by N and T, who developed the Simon Nitinol filter, to -- documents they provided to us when we acquired the rights to that.

The words or the initials, the acronym SNF, for Simon Nitinol filter, and the words Simon Nitinol were used as search terms chosen by Mr. Lopez's firm in the *Phillips* case, and applied to the new custodians he identified, as well as applied to the custodians that had already been searched.

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There is a wealth of material on the Simon Nitinol filter that's already been produced.

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And we met -- I traveled to Phoenix two weeks ago and met in Mr. Boatman's office with him and Mr. Stoller and Mr. Lopez, and I said at that point, we will certainly consider producing additional Simon Nitinol materials, but you need to tell me what you're looking for on top of what you've already been given.

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And I was told, we want everything.

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If they will specify things, we're willing to sit down and talk with them specifically about it. But they have a number of the items that they stood up here today and said, we need these.

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And I respectfully suggest they need to look at the documents in their repository regarding the Simon Nitinol filter, come back to us, and tell us what they want, and we're happy to sit down and try to be reasonable and come up with some sort of additional production that is commensurate with

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the relevance of this filter to this litigation.

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THE COURT: All right. On this issue, I'm going to have the parties address specific categories of information the plaintiffs want in the matrix that you all are going to be giving to me.

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So, Mr. Lopez, I want you to be precise as you can about exactly what you think you need from the Simon Nitinol

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fitter and why, and the defendants can respond in the matrix as to why that's not appropriate.

And again, we'll be talking then about specifics that will help me make a decision. If needed, I'll get you on the phone. If I think I can rule on the basis of the matrix, I'll rule. That's what we will do to address the Simon Nitinol.

It may be that we need to do the same thing on the recovery cone removal system.

I have the same question, Mr. Lopez, that I did on earlier issues, which was if we'd gone to trial on cases against Bard on these removable filters, why is it — and if the recovery cone is a significant issue, or the recovery cone removal system, why is it that the discovery wasn't done in those cases? May be the same answer as motions to compel were denied, but —

MR. LOPEZ: No, it's a different answer, actually. We didn't know the recovery cone had never cleared it. We're as much in the dark about this as FDA. We didn't know the recovery cone had not gone through the appropriate clearance and approval process to be marketed. We just found that out when we got the warning letter.

The only evidence that this thing was -- Bard calls it a class 1 device, is a memo to file by someone working in the regulatory department at the time.

One of the allegations in this case, and we've got

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evidence to show that it was important for Bard, and this is a Kay Fuller issue as well, to be the first to market with a retrievable device. And in order to be a retrievable device, you would have to have another device that actually could retrieve it.

Well, its two closest competitors that they -- and this is the Kentucky Derby to be first to market. They're literally within months of each other. They both went through a 510(k) process for what their equivalent of the recovery cone, and that -- right now, Bard's going through that same process, and they're seven months into it and they've not gotten that device cleared. Had that -- had they had to go through that same process with those same delays, they're number three in the market. Not number one. They beat their closest competitor by one month, who actually put their retrievable device through a class 2 clearance. It's a much more significant process.

In fact, it took -- just to get the recovery device cleared, they started that process in 1999, 1998. Took them four years, because they went through a class 2 process. And now they've got a retrievable -- their retrievable device just got -- I mean, I have no idea how that got on the market other than the fact it was mentioned in the clearance letter they got from the FDA.

But the FDA has been very clear on this, Your Honor,

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in their warning letter. This just didn't all of a sudden become illegal, adulterated, and misbranded. Their position is this thing should have gone through at least a class 2 clearance back when it was first marketed.

In fact, there's a potential that they make them put it through a full PMA, which means they've got to do clinical trials. We don't know yet. I mean, this is something I can brief, Your Honor, with -- as part of the warning letter, if you'd like.

THE COURT: Well, that might be what we want to do.

There are various categories of information at the top of page 42 that Bard says it has given you with respect to the recovery cones. Do you disagree with that list?

MR. LOPEZ: I wish I could say I agree or disagree.

These depositions literally concluded a week ago, and we've -you know, we've been focusing on really the allegation as -I'm sorry, Your Honor, within the warning letter. So if they
represent this to be true, I'm not going to say that they
haven't given that to us.

But I think the point is here not as much about documents as it is about being able to maybe take some depositions of some of the people who are involved in this process to find out how it was that a device that's clearly class 2 -- when I asked their designee in a 30(b)(6), when I described this, he agreed that the description of this device

is a class 2 device, and that description applied in 2002, 13:56:15 1 2 just like it applies today. 3 But would he agree with me it should have gone through a class 2 clearance process? No. But he agrees it --13:56:27 as described, it is and was and always has been a class 2 device. 6 7 THE COURT: Okay. Let's say you've just said that to 8 the jury in your closing argument. Therefore, what? Therefore, how does that strengthen your case on --13:56:42 10 MR. LOPEZ: Because --11 THE COURT: -- an Eclipse filter? 12 MR. LOPEZ: Because everything that -- on an Eclipse 13 filter? THE COURT: Well, any of the removable filters. How 14 does the fact that you think the device to recover it was not 13:56:53 15 properly cleared with the FDA affect the question of whether 16 17 or not that filter, in place, has caused damage to the plaintiff? 18 MR. LOPEZ: Well, if it's a case where it can't be 19 retrieved and it's tilted and it's embedded, and the device 13:57:09 20 21 was not properly designed to deal with that type of situation, 22 at which -- I mean, there are a significant percentage of 23 cases like that. One of the early remand cases is like that, 24 the Tillman case. 13:57:28 25 And, again, I don't know where FD -- and they may

have clearance today. In fact, I think they're expecting it.

I don't know. All I know is they have a device that we know
is the only device that doctors are being told they should use
to remove a recovery and a G2 device that cannot remove
hundreds, if not thousands, of these once these patients go in
to have the device removed.

I don't know whether that's a design problem with the device, I don't know whether or not that has something to do with the material. We don't know because it never went through clearance with FDA.

So to that extent, it may have caused injury to our clients because now they've got to go to Dr. Kuo in Stanford or they have to go to Dr. Lynch at the University of Pennsylvania and spend three or four days in the hospital with an open procedure versus an outpatient procedure where someone puts a retrievable device and pulls it out and they get to go home. I mean, that's --

THE COURT: Okay. I understand.

MR. BOATMAN: Could I add something, Your Honor?
THE COURT: Sure.

MR. BOATMAN: I think maybe as importantly, in my view, is it shows Bard -- another example, in our view, of Bard ignoring the law and the requirements and taking this product to market. That they were making shortcuts, taking shortcuts, ignoring the law, the regulations, to get this to

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market, just like they did -- and we'll talk about in a few minutes -- with Kay Fuller's warnings that their product was defective.

So it goes to the corporate culture, it goes to their noncompliance and their lack of proper safety attitude in developing and marketing this product.

THE COURT: All right. Thank you.

Mr. North.

MR. NORTH: Your Honor, I think this is the same issue as the Simon Nitinol filter. As the Court indicated on page 42 of the submission, we outlined an extensive amount of materials that we had previously produced concerning the recovery cone, including all the design materials, the instructions for use, all the failure mode and effects analysis that were done, all the risk assessments, marketing, training materials, the 510(k) submission that was made and that notified the FDA how Bard was classifying it.

I strongly -- I could argue the merits, but I won't at this point. My suspicion is the FDA is going to render this issue moot in the very near future.

But the fact of the matter is we have produced a large amount of documents regarding the recovery cone, and the word "recovery" was also one of the original key words used in the ESI searches. So they have a wealth of material.

If they will specify what they want in addition to

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that, we're certainly ready to sit down and talk, but right now they just say, we want materials on the recovery cone.

THE COURT: Do you agree, Mr. North, that there are cases in this MDL where the injury being asserted is that the filter can't be removed with a recovery cone, and therefore the patient has to have a much more invasive procedure?

MR. NORTH: There are cases such as that, Your Honor.

I don't believe there are any cases that ultimately will be able to link that allegation to the recovery cone.

I think it's important to note that the FDA, within days of issuing this recovery — this warning letter in July, specifically advised Bard that they could — we could continue to sell the recovery cone as a medical necessity. So it's been available on the market all along.

And if they, as I suspect they will, do clear this device according to the 510(k) we have now filed at their request, then I find it difficult to see how the fact that Bard classified it one way and, 12 years later, the FDA said, no, you should have classified it that way, could be related to these instances if it's continued to be used and continued to be available and the FDA has since cleared it.

MR. LOPEZ: Your Honor, I'm sorry. I mean, you don't need to hear from me, but I just want the Court to know the reality of why it's available.

The FDA did not say you can continue to sell and

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market the recovery cone. The FDA said if physicians specifically request it because they want to use it to attempt a removal of a recovery cone, you could provide that to them. They're not actively — they're absolutely prohibited from marketing the recovery cone to anybody.

THE COURT: Well, I know you all could debate this issue at length. What I'm going to do is I'm going to ask you, because I need to have a better understanding of relevancy, which to me, again, is key, I'm going to have you include this in your briefing on the FDA warning letter, which is related. I'm going to give you 15 pages instead of 10 so you can address this as well.

And February 10th will remain the date.

But address, again, the relevancy of the recovery cone, specifically what the plaintiffs want, and from the defendants why you think it's not relevant and why you've given enough discovery.

All right. On the next topic, which is sales and marketing personnel, here's my thought. We're going to set before we leave today another case management conference in a couple of months. It seems to me what we ought to do is between now and then have plaintiffs conduct discovery of sales and marketing personnel at the national level.

Once you've done that, then we ought to talk about whether there is a reason to do additional discovery of sales

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and marketing at the regional level.

Let's pick the low-hanging fruit first, the stuff everybody agrees is relevant, and from that we can decide whether we need to go to the regional level.

Does that make sense to folks?

MR. STOLLER: Your Honor, it does. That was our suggestion, I think, let's take these in order, figure out —take it at the top level first.

In terms of timing, I'm not sure how quickly we'll get to the depositions, but at least theoretically approaching in stages makes sense to us. I'm not sure whether we'll be in a position by the time the next one rolls around to say, okay, we need it or we don't, but certainly if we do, we can address it at that time.

THE COURT: Well, let's do this: I'm going to say in my order that discovery of sales and marketing personnel at the national level may proceed. I'm going to leave it to you to come back to me, not a month before the close of discovery, but at some point to say we've done it, this is why we need —well, you'll say it to them first: This is why we need to go to the regional level.

If there's an issue, you'll raise it at the next case management conference. So I won't set an arbitrary time, but I'll leave it to you to tee that issue up if you think you need to go to regional.

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                        MR. LOPEZ: Absolutely appropriate, Your Honor.
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               Thank you.
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                        MR. NORTH: Yes, Your Honor. That's fine.
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                        THE COURT: Okay.
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                        All right. On the pending 30(b)(6) notices, we've
               just dealt with sales and marketing.
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                        Is it true, as the defendants assert on page 45, that
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               the plaintiffs have agreed to withdraw the notice on the
               topics of regulatory affairs and communications?
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                        MR. STOLLER: Your Honor, that's not my recollection,
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              but --
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                        MR. NORTH: You said that at the meeting.
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                        MR. STOLLER: No, I didn't.
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                        THE COURT: Okay. All right, so it's still an issue.
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                        The defendants assert that post-marketing
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               surveillance and the adverse events reporting were subjects
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               that were already addressed in a 30(b)(6) deposition in 2012
              by your firm, Mr. Lopez.
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                        Is that true, and if so, why is that not sufficient?
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                        MR. LOPEZ: I'm trying to think, when was Mr. Modra's
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              deposition?
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                        THE COURT: It doesn't matter if it's 2012 or '13,
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              but I guess the question is why isn't it sufficient and what
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              do you think you need more on this --
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                       MR. LOPEZ: Well, Your Honor, this could probably
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become part of -- because I think is pharmacal -- I mean, it is a pharmacal digital and it's post-market surveillance issue that we're dealing with in the warning letter, Your Honor.

We'll probably ask for a 30(b)(6) that's probably not as generic as this. I'm willing to, unless anyone else objects, to suspend that. Not withdraw it, but at least suspend it awaiting the Court's guidance on the type of warning letter discovery.

THE COURT: What I'm going to do for case management purposes is say it's withdrawn.

MR. LOPEZ: Okay.

THE COURT: Let's address the FDA warning letter. I'll give you guidance on what discovery is appropriate. Then you can confer. And if you have a disagreement on whether a 30(b)(6) in this area is warranted or not, you can raise it with me. But that makes sense to at least have me understand better the FDA warning letter issue.

MR. LOPEZ: All right, Your Honor.

THE COURT: What about this regulatory affairs and communications issue? What is it that you all think you need

MR. BOATMAN: Your Honor, at this point it's sort of going into the area of what additional discovery are we going to -- are we requesting for phase two from this point forward.

And also the genesis of most of this is the discovery

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we want to do in follow-up to the Kay Fuller deposition, both document requests and depositions.

So I don't know if now's the time to go to either of those subjects, but it's sort of one in the same in my view.

THE COURT: Okay. Let's talk about it in that next context, and that's actually the next subject, which is additional depositions of corporate and third-party witnesses.

And this relates to the whole question you briefed separately of what is the effect in this case of discovery you've already done in other cases. Let me tell you my general thoughts on that, and we can then talk about how to proceed.

In terms of the arguments that you made, my view is that this is not a Rule 32(a)(8) issue. Rule 32(a)(8) is not about what additional discovery can be done, it's about how completed discovery can be used. And the question it would raise is whether a deposition done before the MDL can be used in the MDL, not whether that person can be deposed again. So, to me, 32(a)(8) is not the right focus.

I agree that Rule 30(a) allows you to take depositions of parties. However, to me, the key provision is Rule 26(b)(2)(C), which says that I must limit the frequency or extent of discovery if I determine that discovery is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less

burdensome, or less expensive. 14:11:12 1 2 3 4 Rule 26(b)(2)(C). 14:11:30 6 7 8 9 14:11:46 10 11 discovery and do it. 12 13 14 14:12:04 15 16 17 would be duplicative under Rule 26(b)(2)(C). 18 19 14:12:31 20 questions that were asked of the same witness in 2012. 21 22 waste your time doing that either. 23 MR. BOATMAN: That's right. 24 14:12:45 25

Related to that, 26(b)(2)(C) also says I can limit discovery if it's outside the scope permitted by 26(b)(1), which now includes proportionality that used to be in Here's my general view, and I'm inviting your reaction to this. This is a new MDL. We have entirely new cases in it. Cases where no discovery has been done. Although it's true that there's quite a history of discovery, the normal approach in an MDL would be to launch into So it seems to me I ought to start with the presumption that the plaintiffs can do their discovery in the MDL, and I should limit that only if I conclude that other discovery that has been done and is usable by the plaintiffs is sufficient for their needs and that therefore redoing it

It doesn't make any sense, in my view, for plaintiffs' counsel to sit in a deposition and ask the same

And I'm assuming plaintiffs' counsel don't want to

THE COURT: But it may be that given the breadth of this case and the fact we've got new filters involved, given

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other information that's been learned by that deposition, the plaintiffs who have done no discovery in this case, meaning the parties who are actually new plaintiffs, should be able to get from that witness relevant information that wasn't covered in 2012 because it wasn't part of that case.

And the question is how do we walk that path so we're not duplicating stuff, but we're allowing you to do the discovery you need to for purposes of the MDL.

Because of that, I am not thinking, Mr. North, that it makes sense for me to say we'll do ten to 12 more depositions. That, to me, is sort of pulling a number of out of the air, and I don't know if that's right.

So what I'm inclined to do is try to just set up a process by which we can work through this. Something like the following: Plaintiffs can depose witnesses in this case that have not previously been deposed that are relevant.

If plaintiffs want to take a deposition of a person who was previously deposed, then the burden ought to be on the plaintiffs to say, this is why we ought to take this deposition again. Here's the relevant information that needs to be inquired into that wasn't inquired into before. Where there's some other reason that the previous deposition is not sufficient for the purposes of the MDL. Here's how long we think it will take. This is a one-hour deposition or this is a full deposition.

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And defendants ought to be able to look at that witness and say, what you're proposing is a complete duplication, or say you're right, those subjects weren't covered before.

And after that exchange, because I think it's the defendants' burden to get a protective order, if you think that the proposed deposition is too burdensome, then you have to raise it with me and explain why. Otherwise the deposition occurs.

But the idea would be to not just have a deposition notice go out for Mr. Mosier again with no discussion among you. I think the idea is have a discussion about what really needs to be covered that wasn't previously covered, and if it needs to be covered, you absolutely should be allowed to do it. But if it's duplicative, it would be a waste of everybody's time and we're not going to do that.

I'm not anxious to have a witness-by-witness dispute in this case about depositions, but I'm hopeful that you'll all be able to agree on most of them. If not, we may end up at some point appointing a special master to deal with that if I can't do it regularly enough. But that seems to me to be the more sensible way to approach this issue rather than pick an arbitrary number or try to enter broad categories of rulings as to who can be deposed and who can't.

And I invite your reactions. And if you think it's a

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terrible idea, tell me. That's not going to hurt my feelings.

I want the get the best result here.

MR. BOATMAN: Your Honor, I think that's a very good procedure. It's sensible, it's logical, and it balances the competing interests that we're looking at.

I have a couple concerns in the details. And I hope we can work through it, but let me give you one example.

There are going to be several instances where people have been questioned on a subject matter that we're going to want to question them again, and it's going to be because of new information. So, for example, people that have already been deposed, we may want to cross-examine or have additional questions for them concerning their prior testimony in light of the fact that we've now learned that they had 300 unreported serious injuries, for example.

We may want to question them on their previous testimony regarding the development of the recovery filter in light of Kay Fuller's testimony that they ignored her warnings that the product was going to hurt and kill people.

So it goes -- I don't think we can have it quite as simple as if you've covered a topic, you don't get to back into that topic because old topics are going to be -- need to be readdressed in light of new information and testimony.

But conceptually I agree, and I just wanted to be clear that -- that the -- it seems to me that I think the

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approach you suggested is right. By and large, we should be able to work that out.

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I just don't want to have a situation where once a deposition's under way, there's a dispute, having to get the Court on the phone or an instruction to a witness not to answer that because this is a subject matter that has already been addressed.

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The other concern I have, Your Honor, and maybe we'll deal with this separately, is in some instances we may be viewing these depositions as trial depositions. And to the extent we're going to do that at one time instead of in two steps, sometimes you might want to go over some previous answers just to put the new part or to put things in context or for flow. I suppose we could edit prior depositions to the extent we have them all on videotape.

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THE COURT: Well, on that point, Mr. Boatman, would you be willing to stipulate that if you are taking a trial deposition where you're going to cover some old ground, you

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will not call that witness live at trial?

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a trial deposition, the quid pro quo should be that's your

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shot at it. What you shouldn't be able to do is do that, and

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then decide when you get to trial, no, we're calling this

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witness and therefore we're going to do it for a third time.

It seems to me if you want to re-ask questions to get

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MR. BOATMAN: And the problem I have with that,

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Your Honor, is -- I think that's fair, and, again, you're being reasonable. I guess two concerns. One is that I'm a little reluctant to speak on behalf of all of the other attorneys.

And, secondly, there may be instances where it's a trial deposition in Wisconsin where the witness is unavailable, or we can't subpoena, for example, a Bard employee, and that's primarily who I'm talking about. So there may be an instance where one of us in a bellwether case wants to call a Bard employee live instead of playing a tape in Arizona, but we still want to have a trial deposition to use in a case in Wisconsin or wherever.

So I think we can work through that. I'm just raising that as a concern.

THE COURT: Well, an interesting question I hadn't thought of before is this, and maybe you all have experience: What happens in an MDL after the cases have been remanded, they go back to their home states, and the plaintiff in that home state says, we can't subpoena a witness who was deposed in the MDL, therefore we want to take a trial deposition of that witness before the trial in this state? Is there a law that says you can't do it because you were able to depose them in the MDL and that was your shot? Or do people have the chance, when they get home, to go do trial depositions? If so, then we shouldn't be doing them here.

I don't know the answer to that.

MR. BOATMAN: Yeah, general --

MR. LOPEZ: I'm just going to segue you're talking about in another federal court or state court case,
Your Honor?

THE COURT: Well, it would be federal court because it's the MDL. But my point is if a case from here goes back to Wisconsin, will the plaintiffs' lawyer at that point say, you know, Mr. So-and-so from Bard was deposed in the MDL as a discovery deposition. We want to do a trial deposition here in Wisconsin so we can present him to the jury, and we can't subpoena him to Wisconsin, therefore let us go do a trial deposition. Or will the judge then say, you had your shot in the MDL, we aren't doing any more depositions here.

In other words, should we really undertake the task in this MDL of having us do all the trial depositions that may be needed in all of these cases after remand?

MR. LOPEZ: I would say this: I mean, some jurisdictions, you actually have to notice a trial deposition. You can't use the actual discovery deposition. But I like what you just asked at the end. I think that if we're allowed to do trial depositions, and here again, this is a unique case with a unique opportunity to be able to do that because we do have history of depositions, not just taken by my firm or other firms but people who aren't even here, to focus on

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having a lot of these former depositions actually be trial depositions.

I mean, I use these depositions at trial, and there's a lot of reasons why I would not want to play some of these depositions to a jury, but some of it has to do with the way I sound in the deposition, and a lot of it has to do with the fact that we didn't have a special master there, where you're having to ask the same question over and over again.

So I like the idea, and I think we --

THE COURT: Well, I haven't proposed it.

MR. LOPEZ: I know. It's still a good idea, Judge. I mean I think I -- maybe a hybrid of that. I mean, some of this will probably have to be discovery because we haven't taken a number of depositions, but I think that might be a good vehicle, this MDL, to maybe avoid people that do get remanded from having to say, well, I didn't like the way Lopez's voice was on this videotape, I want to take a two-hour trial deposition, or I don't like the way the witness is responding or he didn't respond.

So I think that's worth exploring. I think it's a really good idea, especially with some -- obviously, the depositions we did take are some of the -- you know, people in certain positions with the company that would be important for us to want to use at trial. Some are just not very good for trial purposes. We ended up reading three or four of these in

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our *Phillips* trial in front of Judge Jones because the videos were just a disaster.

MR. KELLY: Yes, Your Honor, thank you. I am not lead counsel. My name is Michael Kelly. I'm a lawyer for a plaintiff in this matter.

And I simply wanted to say that there are skilled lawyers, as the Court has observed, who have been working on this for years. But my case comes late to the party, as do many of the other lawyers.

And I think we agree with the Court's inclination, that is to treat this MDL as though it is a new MDL. And I assure the Court that I have no interest in asking the very same questions someone else has asked. I don't have that much sand left in the top of my hourglass to waste my time on stuff that's not worth doing.

I think these management questions are appropriate questions, and I think, in my own experience, individual trial court judges will handle the question you asked about preserving testimony or using trial testimony differently.

I do think the courts default to let's treat this like it's a new MDL. Let's not have you, or hopefully even a special master, micromanage what question and what person.

These are good lawyers, these are ethical, professional people. We ought to be able to work this out.

And the individual small questions about who should

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be redeposed, what should be a trial deposition, I think is probably something that's 180 to 300 days away, maybe, while we try and get the information. I think that is necessary on liability, on general causation, on notice for those persons that we, on the plaintiff side, believe have relevant information, and that would be helpful.

And so I offer that only to say I appreciate the Court's insight to the fact that we haven't participated in anything, and my ethical obligation to my client, my one client, is to make sure that we do the best job, that I don't tell her I'm relying on some people I've never met before who have taken depositions for years.

Thank you.

THE COURT: All right.

MR. DALIMONTE: John Dalimonte here. I don't know if --

THE COURT: Yeah, folks on the phone won't hear you,
Mr. Dalimonte, if you're not on a mic. You can pick up the
one next to Mr. Stoller if you want to --

MR. DALIMONTE: I just simply want to say as far as the trial depositions, if we were to remand a number of cases over time, eventually there may be 20, 30, 40, 50 cases remanded. If we were to remand these outside the jurisdiction of where these witnesses reside, then potentially these same witnesses could be deposed repeatedly for purposes of having

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trial videos done, the trial depositions. So it makes sense to have it done here through this MDL.

THE COURT: Mr. North.

MR. NORTH: Yes, Your Honor, I have a number of comments.

I understand the Court's reluctance and unwillingness to impose a numerical limitation. And I also agree with the Court that as of now, the issue as framed, it's really a matter under Rule 26 as opposed to Rule 32.

What I am concerned -- and I think the procedure the Court has suggested makes perfect sense as long as the plaintiffs are specific when they come back to us and tell us exactly -- not question by question, but topically, what they want to address in a follow-up deposition of somebody that's been deposed.

What I'm most concerned about, though, is where we're going to be six months from now. In some initial discussions, the plaintiffs have suggested to me and given me a list,

Mr. Lopez did, of approximately 25 deponents he wanted in addition to -- well, 25 to start with, and has made it very clear that that's just the beginning.

I understand this is an MDL and there are large -you know, almost 200 cases now. We don't know how many are
coming. The proportionality needs to be defined against that
background to some extent. However, what concerns me is we

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have a background now of over 80-plus corporate depositions that, by the plaintiffs' own concessions, can be used here, and I'm fearful of the prospect that we're going to be confronted with requests to take 80 to 100 more. I don't know where the ultimate number is going to be.

But, again, I think the process the Court has proposed makes sense. We're certainly willing to do it. I'm just fearful that several months from now I'm going to be here and saying, Your Honor, in our view, enough is enough. No matter how many cases there are, proportionality has to come into play at some point, and when you've already got 80 depositions, many of them taken by the same attorneys, and now you're at 25, 30, 50, 80 more, at some point there has to be a stopping point. And so that's my concern.

THE COURT: Okay. Well, let me throw out one other idea on this topic. One thing we could do to create correct incentives and to keep some control on the amount of deposing we do in this case is set a total hour limit. Say, for example, that as a start, plaintiffs have 100 hours to do depositions. And what we will do is as we approach that 100 hours, we'll revisit it and see if it needs to be moved to 150.

The idea behind this is simple, which is it creates real incentives in the deposition to be as efficient as possible because the questioning lawyer knows every hour you

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spend in this deposition, you won't be able to spend in others. It eliminates time wasting to a significant extent.

It allows -- if you have 100 hours, in theory you could depose 50 witnesses for two hours, or you could depose ten witnesses for ten hours. You can allocate it in terms of witnesses.

I don't know if that's a good idea in this case.

I've seen cases where it really helped. But it would get, at least to some degree, at the proportionality issue. It wouldn't be a hard limit, but it would be a presumptive limit, and there would need to be good justification to increase it.

Maybe it's a real bad idea. But I invite your thoughts on whether that makes any sense.

MR. BOATMAN: Your Honor, I think your initial proposal did a better job of balancing the interests because, at least as I understand your proposal, if I go to Mr. North and say I want to take Robert Carr's deposition, and he's going to say, no, he's already been deposed, you know, four or five times, whatever it is -- he's the chief engineer on this case -- and I say, yeah, I know, but I have issues to cover, I think it's going to be caught in that process you've designed of him then coming to you and saying, no, it's unreasonable, this witness is unreasonable.

There's a lot of people who are now people that have never been deposed, and I don't know how long they're going to

take. There's third-party people that's going to be 14:30:53 1 2 cross-examination of by the defendant. 3 We've had a problem in the past, Mr. Lopez's firm 4 has, where they've requested a special master because the 5 witnesses were very slow to answer questions. And so I 14:31:09 think -- and I think having a clock running just sort of 6 7 encourages that sort of obstructionist sort of answering. 8 And so I think between the proposals, I think the 9 safeguard that the defendants are requesting are contained in the -- your initial proposal. 14:31:30 10 11 THE COURT: Thanks. 12 Any comment, Mr. North? 1.3 MR. NORTH: Your Honor, I am personally a proponent 14 of time limitations on both parties. I see the increasing trend of many federal judges to put time limitations in trials 14:31:48 15 16 on the parties. And I think it does incentivize everyone 17 concerned to be efficient and appropriate. So we would heartily endorse some sort of presumptive 18 limit, understanding that, you know, it's not cast in stone. 19 THE COURT: All right. We'll take a break after 14:33:25 20 21 this. 22 What I'm going to do on this issue is, in my order I 23 am going to specify the procedure I described a minute ago. 24 I'm going to say -- first of all, that witnesses not 14:33:45 25 previously deposed that are relevant may be deposed in the

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case, just like in any other case.

Secondly, for witnesses who were formerly deposed,

I'm going to require plaintiffs to provide to defendants a

description of why the deposition is needed and whether you

think it's one-hour or a five-hour deposition, recognizing

it's just an estimate, so they at least have a sense.

If defendants are of the view that that is a deposition that shouldn't be permitted under Rule 26(b)(2)(C) and the criteria in it, they can make a request of me to not allow it. But I'll apply what's in 26(b)(2)(C), which is I'll only disapprove the deposition if it's unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive. So the burden will still be on the defendants to get the protective order.

What I'm going to do is identify some categories that I think would clearly be appropriate, such as there's a filter now in the case that wasn't in the case at the time the witness was deposed. So an entirely new topic. Or some reasonably significant new information on an old topic that's been discovered and ought to be inquired into.

I won't be able to be too definitive, but I want to give some guidance on where I think clearly the deposition should be warranted so that will help you in your discussions.

And when you reach the point where the plaintiffs

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want one of these witnesses and the defendants disagree, and try to talk about it in bunches so we don't do a call for every witness, call me. I'll get you on the phone, and we'll see how it's working. If it's bogging down, maybe I can provide clearer guidance on what's allowed. Maybe at some point we need to get a special master involved. I'd like to avoid that. But we'll see how it works.

I think reasonable minds can clearly identify witnesses where there ought to be another deposition, because this is a much larger case now with more filters, and we'll just see -- you'll get a sense as we go along as to how I'm ruling. Maybe that will help you reach agreement.

I'm not going to impose an overall hours limit. I don't think that's a good idea in this case. But that's what I'll spell out, and we'll see how it works.

And when you have some witnesses you disagree on,

I'll leave it to defendants to initiate the call, get

plaintiffs on the line, call us, we'll get a time scheduled

and get you on the phone, and I may in those calls have you do

a matrix. I find those are very helpful in getting parties to

talk about the same issues if I can't tell whether or not the

witness really was questioned extensively on a subject. But

we'll approach that as we should.

I think this takes us through all of the issues in the joint report. Because we've already talked about

14:36:56 1 discovery on ESI preservation. 2 So when we come back, what I want to talk about is 3 discovery regarding the Kay Fuller allegations, early consideration of plaintiffs' equitable tolling arguments, and then some of the -- well, and the privilege log issues. Those 5 14:37:12 are the primary ones, and then there's some other housekeeping 6 7 matters. 8 So let's get back together at ten to the hour. 9 (Recess taken from 2:37 to 2:52.) 14:52:25 10 THE COURT: Please be seated. 11 On the Kay Fuller issue, I'm having some of the same 12 difficulty that I had on the FDA warning letter, which is I just don't know the significance of her allegations because I 13 don't understand the case fully yet. Or even partially yet. 14 Seeing as it's five to 3:00 on a Friday afternoon, 14:53:14 15 maybe we ought to -- maybe we ought to do this: 16 17 defendants agree in the report that Edwards and Vierling, V-I-E-R-L-I-N-G --18 19 MR. NORTH: Yes. THE COURT: -- can be deposed. 14:53:32 20 21 MR. NORTH: Yes. 22 THE COURT: So we ought to say those are okay to go 23 ahead with. There's disagreement on whether the five 24 additional witnesses that the plaintiffs proposed should be 14:53:42 25 deposed. I need a better sense for the importance of this

issue. I hate to make that brief much longer, but maybe we 14:53:45 1 2 ought to add the Kay Fuller issue to it, the one that's going 3 to be filed on the 10th, and make it a 20-pager instead of a 4 15 -- well, do we need it that long? You tell me. 14:54:01 were to write this really efficiently, can you cover the FDA --6 7 MR. STOLLER: 45 pages, Your Honor. 8 THE COURT: What was that? 9 MR. STOLLER: I said 45 pages, Your Honor. 14:54:12 10 THE COURT: That just doesn't sound funny at 3 p.m. 11 on a Friday afternoon, Mr. Stoller. 12 MR. NORTH: Your Honor, I'm sorry to interrupt, but I 13 may have an easier proposal, at least something the Court 14 hasn't --THE COURT: I'm all for easier proposals. 14:54:21 15 16 MR. NORTH: The other three people they've listed 17 besides Ms. Edwards and Ms. Vierling, and Ms. Edwards has been deposed before but Ms. Vierling hasn't. Ms. Edwards was never 18 questioned about Kay Fuller specifically, as I recall. The 19 14:54:36 20 other three people have already been deposed. Why can't we just wrap those up in what we were talking about last time? 21 22 And if they want to redepose any of those three 23 during the course of this, they can let me know and tell me 24 the same things that the Court is going to put in the order 14:54:50 25 that they should if they want to redepose somebody. And if

it's about Kay Fuller, and they haven't really deposed them about that before, that's probably fair game, then.

MR. BOATMAN: Yes, Your Honor, but I was up very late putting together my Kay Fuller presentation.

THE COURT: I'm sure your wife would love to see it this evening.

MR. BOATMAN: Your Honor, I do think that your ruling on the scope of future discovery handles this, because the people that haven't been deposed will be deposed, the people that have been deposed that need to be redeposed concerning what they're going to say about Kay Fuller, I think clearly fall within that exception.

THE COURT: Okay. Then I think you're agreeing with what he said; right?

MR. BOATMAN: Yes.

THE COURT: Okay. So what we will do is we'll say that Edwards and Vierling can be deposed, and as to other witnesses that you think ought to be deposed, go through the same discussion. If defendants think it's not appropriate, then you can — the defendants can seek a protective order through a call, the way we discussed.

All right. Early consideration of plaintiffs' equitable tolling arguments.

Mr. North, some questions for you. I haven't read what Judge Seibel, S-E-I-B-E-L, or Seibel, did in the IUD

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case, but — and maybe I'm not understanding the equitable tolling issue correctly, but it seems to me if the question I'm answering is whether a particular plaintiff's claim that you believe is untimely can obtain equitable tolling of the statute of limitations, I need to look at more than allegations about what Bard did. I need to consider what the individual plaintiff knew or should have known.

It's an equitable defense, so I need to -- or an equitable argument on behalf of the plaintiff. I need to look at whether there are equitable reasons that this particular plaintiff should or should not be able to avail themselves of equitable tolling. I don't know if state law governs or not.

I guess the question is can I enter a global decision in this MDL that either grants or denies all of the plaintiffs the right to assert equitable tolling?

MR. NORTH: No, Your Honor, and this Mirena proposal did not do a global decision. What it did, though, was set up a process of doing a very finite number of test cases that the parties could then have an abbreviated procedure afterwards to try to resolve as many of these issues as possible.

It's somewhat unique, but it did work in the Mirena litigation. And I told Mr. Boatman and Mr. Stoller recently that we just weren't quite to the point — we were trying to see the filings come in and see the latest influx, but that I would sit down and speak with them about the proposal, see if

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they could agree to it when we could specify it in a little more detail once we see the filings, and then bring it the Court.

I just wanted to flag this for the Court's consideration. We certainly will not be wasting time and delaying too much on getting that. But it's something for the Court to consider. I understand there may be a presumptive view that, oh, this is state law specific, but I do think it has certain benefits and can be done with just a little bit of foray into state law, as opposed to a massive, massive attempt to navigate those waters.

And so we'd like the opportunity to at least discuss it with the plaintiffs and bring it back to the Court's attention later, if appropriate.

THE COURT: All right. That's the way we'll leave it, then. You can raise it with the plaintiffs, and if you need me to address it, I'll leave it to you to raise it with me.

counsel, when I look at the motions pending in existing cases as described in Exhibit 7, we're dealing with fairly case-specific issues in some of them, such as a motion to reopen discovery, a motion to compel and extend the discovery deadline. There are expert-specific motions to exclude particular experts. There is the Lehmann motion. There are some motions for summary judgment.

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Why isn't the best course just to deny all of these without prejudice so they're off the dockets, they're not encumbering the MDL? Some of them are going to be decided in the MDL proceeding, such as the Lehmann issue, the expert issues.

I would say in the order that they're being denied without prejudice to Bard reasserting a summary judgment motion if the case is remanded, in other words if it's addressing issues that aren't resolved in the MDL, so you're not being prejudiced, and we just sort of clear out this underbrush and not have to deal with it in the MDL.

Does that create problems for either side?

MR. LOPEZ: I was going to ask you to pend them until some -- but denying them without prejudice is the same thing.

MR. NORTH: I don't think that's a problem,

Your Honor. I will glance through them quickly and let the

Court know if -- I think there may be an exception to that,

but otherwise I think that works.

THE COURT: Okay.

MR. BOATMAN: It would be true also for the pending plaintiffs' motions, right, Your Honor? For example, the plaintiffs could come back and seek to reopen discovery or extend discovery deadlines?

THE COURT: Well, yeah. I mean, all of it would be denied without prejudice. So, you know, if you get back to a

15:00:54 1 state on remand and there's still some case-specific discovery 2 you think is needed that wasn't addressed in the MDL, it 3 wouldn't foreclose you from asking that judge for it. All right, that's what we'll do with the pending 4 15:01:07 5 motions unless you point something out, Mr. North, that's a problem. 6 7 Privilege log. I haven't read, for good reason, yet 8 either the Vioxx or the Phillips orders. They're very long. 9 Mr. Boatman, you have something you want to say before --15:01:29 10 11 MR. BOATMAN: I do, Your Honor. I think I have good 12 news for you. Over the last couple of days, our committee chair on the privilege logs and the people with Mr. North's 13 office have continued to work through a protocol, and they 14 have reached a proposal that they've recommended to lead 15:01:46 15 counsel and to Mr. North. Unfortunately, we got that proposal 16 17 last night, and Mr. North was getting into town and everybody 18 was working very hard getting ready. So I think -- I hope we're going to be able to work 19 it out ourselves, and we'd ask that the Court give us a week 15:02:05 20 to let you know if that's the case or not. 21 22 THE COURT: Mr. North. 23 MR. NORTH: Yes, Your Honor. 24 THE COURT: Okay. 15:02:15 25 MR. NORTH: Apologize. I just did not see that

proposal until after I got off the plane last night. 15:02:17 1 2 THE COURT: That's fine. 3 Is a week enough time? MR. NORTH: Yes. Definitely. 4 15:02:28 5 MR. BOATMAN: Yes, Your Honor. THE COURT: Okay. 6 7 So if you don't work it out in a week, then what I'm 8 going to do is probably get you on the phone to talk about 9 what we ought to do with it. But I'm going to have -- I'm 15:02:40 10 going to say in the order you'll let me know in a week whether 11 that issue is resolved, and, if so, how it's been resolved. 12 Okay. Couple of other matters. At Docket 435, there's a stipulation to submit fact 13 sheets later in connection with the bellwether process. Case 14 Management Order 5 had required those by January 15th. 15:03:05 15 When you are stipulating to deal with them in the 16 17 bellwether process, is that the March 1st proposal that you're 18 going to make? Is that the idea? 19 MR. NORTH: Yes, Your Honor. Since those would be 15:03:18 20 tied to only cases that would be part of a bellwether process, 21 we thought it might be best to lump it all into the same 22 proposal. 23 That's fine. Okay. So I will grant the THE COURT: 24 stipulation, and we'll look for your facts sheet suggestions 15:03:34 25 as part of that March 1st proposal.

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Docket 438 is your stipulation on electronically stored information. It looked fine to me for purposes of the form of production, redaction, duplication like this. It didn't say anything about preservation. That was the one of the subjects.

And what I was thinking about in particular was whether there should be any sort of order on preservation, particularly with respect to plaintiffs. You've got folks coming into the case all the time. Should there be anything in the case management order about the fact that plaintiffs will take certain steps to try to preserve relevant information?

MR. STOLLER: Can I approach the podium?

THE COURT: Yeah.

MR. STOLLER: Mr. Lerner and I have been exchanging a little more information on that issue. My suspicion is or hope is that maybe the parties will work something out on it. We have not to date. But we started -- frankly, I've asked them to start to identify the things that they're going to ask for, and then move to the next step of figuring out what form that would take. We had discussed possibly sending out a letter, but if you'd like to put it in the form of a CMO, I think the parties can continue to work towards a stipulated form in that order.

THE COURT: Well, why don't we do this, then: I will

15:04:56 1 approve and enter the case management order that you've 2 already stipulated to. But let's set a date by which you'll 3 get back to me on whether there's an additional stipulation on 4 preservation that we will -- we will in effect add as an 15:05:13 appendix to this order or a second order that refers back to it. 6 7 Does that make sense? 8 MR. NORTH: I think so, Your Honor. 9 MR. STOLLER: It works for plaintiffs, Your Honor. 15:05:22 10 THE COURT: Okay. That's fine. 11 How much time do you need for that? 12 MR. STOLLER: Two weeks. 1.3 MR. NORTH: Two weeks. 14 MR. STOLLER: Two weeks work for you, Your Honor? 15:05:32 15 THE COURT: Yeah, that's fine. I'm going to try to 16 synthesize these dates in the order so we don't have ten, 17 we've got just a couple, but I will make it approximately that far out. 18 Brief report from the plaintiffs on the status of 19 15:05:47 20 coordination with state court actions. Can you give me a sense for that? 21 2.2 MR. STOLLER: I think the short answer, Your Honor, 23 I'm going to give you in broad strokes in terms of state court 24 stuff, but for most everything in the state court in 15:06:03 25 accordance with what had happened here, we stayed discovery in

just about everything, at least terms of the -- with some 15:06:06 1 2 small exceptions for case-specific discovery in some of the cases. There have been, in a couple of cases I think you guys 3 had entered CMOs for timing in Austin. MR. NORTH: Yeah. 15:06:21 5 6 MR. STOLLER: But I don't think there's been any 7 ongoing discovery outside of the MDL other than case-specific 8 discovery to this point. I think we'll have to do a little bit further coordination going forward now that there's more 15:06:32 10 open discovery. 11 MR. NORTH: That's true. There is nothing in state 12 court actions that are conflicting with what's going on here at this moment. Again, there have been doctors' depositions, 13 plaintiffs' depositions. A number of the cases been stayed, 14 15:06:44 15 as Mr. Stoller said. 16 THE COURT: Okay. Is there going to be a need to try to get agreements in the state court actions that the 17 discovery in this case, for example, on experts or things like 18 19 that will apply in those cases? MR. STOLLER: Well, I think for them to -- for it to 15:07:00 20 21 be effective in those cases, it will have to be an agreement 22 on a case-by-case basis. 23 THE COURT: Right. 24 MR. STOLLER: And I know that, for example, some of 15:07:09 25 them have different deadlines. I think your deadline in

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Austin is different than what we have here, for example.

MR. NORTH: Yeah.

MR. STOLLER: So I think we have to deal with those, Your Honor, on a case-by-case basis.

THE COURT: My primary concern was about conflicting discovery, and it sounds like that's not a problem. But I would encourage you to get as many people to jump on this bandwagon as you can to save time and money in terms of expert discovery or other common discovery, and just keep working with them on that issue.

MR. NORTH: In all of our active state court cases, the plaintiffs' attorneys are actually members of the steering committee here. So there should not be a problem, I would hope. We have a couple of other cases with outlier firms that are not involved here, but those are basically dormant at this point.

THE COURT: Okay. Thanks.

MR. LOPEZ: Your Honor, may I make just one comment on state/federal coordination? I think it's -- while most of that will happen in MDLs, there are going to be some state courts I think they identify that might be a little ahead of us, might have different issues, might have already originated or initiated some discovery.

I think in that regard, we as an MDL will agree to coordinate with them. It doesn't always have to be with the

state court coordinating with what we're doing. If they've got something going on that's unique and we want to do, you know, our efforts are going to be to do it with them.

THE COURT: That makes perfect sense to me.

All right. I have reached the end of my list. I will tell you that I don't think we should come back and do our arguments about the FDA warning letter. I'm just sort of tired.

MR. NORTH: Thank you, Your Honor.

 $\ensuremath{\mathsf{MR}}\xspace$  . LOPEZ: My wife's going to have to listen to mine, then.

THE COURT: I'm sure it will be brilliant.

Do plaintiffs' counsel have other matters that you want to raise while we're here?

MR. BOATMAN: No, Your Honor.

MR. NORTH: Just one thing I wanted to flag for the Court's attention. It's not something to be decided right now, but the Court had inquired at the first conference whether there were any remand motions. And there still are not pending here, but there are two cases where, in response to a motion to remand, the various federal court judges have stayed proceedings pending a decision from the JPML whether to transfer the case here.

The JPML almost always transfers cases over objection, even when there's a remand motion pending. They

15:09:35 1 met yesterday. So I suspect those cases will be transferred 2 in the next week or two if things go as they usually do, and then the Court will have a couple of remand motions pending 3 here. 15:09:44 THE COURT: Okay. All right. Let's talk about the next case management 6 7 conference. 8 (The Court and the courtroom deputy confer.) 9 THE COURT: All right. Counsel, I think what I would like to do, just so that I stay in touch with this case, is 15:13:57 10 11 hold another case management conference in two months. It 12 doesn't need to be long if there aren't a lot of issues, but 13 if so, at least we'll be able to get them resolved. 14 So I'm looking at Thursday, March 31st, as a date for the case management conference. Does that cause serious 15:14:15 15 problems for lead counsel on either side? 16 17 MR. NORTH: Fine with me, Your Honor. 18 MR. LOPEZ: We're good, Judge. We're good; is that right? 19 15:14:38 20 MR. BOATMAN: Yeah. THE COURT: Let's set it for 10 a.m. on the 31st. 21 22 I'm going to ask for another joint report to be provided 23 several days in advance. I'll just identify a reasonable date 24 in the order that I enter. 15:15:03 25 And as we approach it, if it's looking like there

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               just aren't that many consequential issues to justify us all
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               getting together, feel free to call my office and suggest we
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               do it by phone. I don't want to make you all come out here if
               it's a one-hour discussion of some issues that aren't pivotal,
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               but I want to make sure we've got the time available if there
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               are important things to resolve to keep the case moving.
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                        Anything else we need to address before we break?
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                        MR. BOATMAN: No, Your Honor.
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                        MR. NORTH: Nothing, Your Honor.
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                        THE COURT: All right. Thanks very much. Have a
               good weekend. Safe travels to you all.
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                    (End of transcript.)
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CERTIFICATE I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona. I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability. DATED at Phoenix, Arizona, this 8th day of February, 2016. s/ Patricia Lyons, RMR, CRR Official Court Reporter